Table of Contents: Supporting Documentation for the July 12, 2013 Lower Willamette Group Combined Notice of Objection to and Request for Dispute Resolution of EPA's Notice of Demand for Payment of Stipulated Penalties Regarding Baseline Human Health Risk Assessment and Request for Determination; Lower Willamette River, Portland Harbor Superfund Site

EXHIBIT #	Date	Document Title
1	October 12, 2012	EPA submission to Director Dan Opalski in response to Lower Willamette Group opening submission, dated September 21, 2012
2	August 1, 2012	Email from D. Yamamoto to B. Wyatt Re: Confirmation of Extension for Informal Dispute Resolution
3	July 27, 2012	Email from L. Cora to S. Parkinson Re: Portland Harbor BHHRA Dispute, attaching 2012-07-27 Basis for Noncompliance
4	September 6, 2012	Email from C. Grandinetti to B. Wyatt Re: confirming that the 17 items comprised the entire basis for the notice of noncompliance
5	October 24, 2012	Lower Willamette Group Reply to EPA Submission Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket No: CERCLA-10-2001-0240
6	December 6, 2012	Formal Dispute on the EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Baseline Human Health Risk Assessment and Request for Dispute Resolution: Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240- Final Resolution - Director Dan Opalski
7	August 1, 2012	Email from B. Wyatt to D. Yamamoto Re: agreement to work from EPA's version of the Baseline Human Health Risk Assessment
8	March 15, 2004	EPA Conditional Approval of RI/FS Work Plan
9	June 30, 2011	EPA Options for Responding to Deficient Deliverables from PRPs Memorandum
10	August 30, 2012	Email K. Koch to B. Wyatt Re: EPA incorporated resolutions to PH BHHRA
11	February 16, 1984	EPA General Enforcement Policy #GM-21
12	September 30, 1997	EPA Interim Policy on Settlement of CERCLA Section 106(b)(1) Penalty Claims and Section 107(c)(3) Punitive Damages Claims for Noncompliance with Administrative Orders Memorandum

EXHIBIT 1

EPA RESPONSE TO LOWER WILLAMETTE GROUP OPENING SUBMISSION, dated September 21, 2012.

I. INTRODUCTION

Ten parties[1] signed the Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, U.S. EPA Docket Number CERCLA-10-2001-0240, which became effective on September 28, 2001 ("AOC"). The AOC was amended on June 16, 2003 and April 27, 2006. [2] The primary objective of the AOC is for the performance of a Remedial Investigation ("RI") and Feasibility Study ("FS") for the Portland Harbor Superfund Site and reimbursement of government oversight costs. The AOC and Statement of Work ("SOW") are attached as Exhibit 1.

Section IX. of the AOC provides the process for approvals and modifications of deliverables produced under it. In accordance with that Section, EPA has the right to "comment on, modify, and direct changes for all deliverables in writing." *See* AOC, Section IX, Paragraph 1. Additionally, ". . . Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables ...." *Id.*

Respondents were required to produce a Baseline Human Health Risk Assessment ("BHHRA") under the AOC and SOW to be approved by EPA. *See* AOC Section VIII and Task 5 of the SOW, Section 7.8.3. The first draft BHHRA was submitted to EPA on September 23, 2009, Exhibit 2 hereto. EPA extensively commented on the first draft BHHRA over a span of about eight months, *see* Tabs 5, 7, and 8.[3] Additional comments were provided after the July 2010 comment set, *see* Tabs 6, 10, 12, 13, 14, 23, and Exhibit 3.[4] Meetings were conducted to discuss EPA's comments by issue category, rather than by specific comment, *see* Tabs 9 and 11. The meeting discussions were focused on the comments that the Respondents had issues or questions

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[1] The ten signatories to the AOC are: ATOFINA Chemicals, Inc. (now Arkema, Inc.), Chevron U.S.A. Inc., Gunderson, Inc., Northwest Natural Gas (now NW Natural), City of Portland, Port of Portland, Time Oil Co., Tosco Corporation (now ConocoPhillips Co.), Union Pacific Railroad Company, and Oregon Steel Mills, Inc.

[2] The 2003 and 2006 AOC amendments did not change the order provisions relevant to this dispute and, therefore, will not be further explained or discussed in this Response.

[3] References to Tabs are to the Supporting Documentation for the September 21, 2012 Lower Willamette Group Opening Submission. Additional supporting documentation being submitted by EPA is attached to this Response Brief as Exhibits.

[4] The record clearly shows that a series of comments and responses on the draft BHHRA were ongoing from December 2009 until April 11, 2011; therefore, Respondents' contention that EPA's July 2010 comprehensive comment set was the last and final comments they expected from EPA on the second draft BHHRA is not reasonable. Also wholly unreasonable, is Respondents' interpretation of EPA's use of the phrase "comprehensive comments set" in that July 2010 letter to mean that EPA would not provide any comments or seek any more changes to their next draft of the BHRRA.

about. The Respondents produced tables with summaries of the understandings reached in the meetings or otherwise how they intended to address some, but not all, of the comments, *see* Tabs 9 and 11. On each table, EPA reviewed their summaries and generally agreed with the approach proposed, but clearly stated that EPA would have to see the revised document before determining whether all comments were addressed.[5]

The second draft BHHRA was submitted to EPA for review and approval on May 2, 2011, *see* Tab 15. After EPA's initial review of the document, EPA notified the Respondents on July 21, 2011 of the intent to modify the BHHRA and requested all word files of the document, *see* Tab 18. The Respondents immediately contacted EPA project managers for fear of EPA work takeover. EPA subsequently sent an email on July 22, 2011, *see* Tab 19, clarifying its intent to modify the document and not take over the document. On June 22, 2012, consistent with the AOC (Section IX, Paragraph 1), EPA transmitted to the Respondents its modified BHHRA text, directing them to accept the modified text and to make necessary changes to tables and figures, *see* Tab 16.

The AOC, Section XVIII., Paragraph 1, provides a dispute resolution process to the Respondents for "[a]ny disputes concerning activities or deliverables required under this Order...." On July 27, 2012, the Respondents notified EPA that it was disputing EPA's modifications made to their second draft BHHRA, *see* Tab 22. In accordance with the dispute resolution process, informal discussions occurred starting on July 27th with the hope of resolving the dispute. EPA is pleased that many issues initially raised by Respondents have been resolved, *see* Tables 1 and 2. The informal dispute resolution process was successful in narrowing down the issues significantly. Unfortunately, not all of the Respondents' issues were resolved to their satisfaction.

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[5] Tab 10, EPA's letter, dated September 22, 2010, states: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome. . . . **Because we did not discuss all the directed comments, a final determination that the LWG has addressed the directed comments can not be made until a redline-strikeout version of the BERA and BHHRA reports are submitted (emphasis added).**"

Likewise, Tab 11, EPA's letter, dated November 18, 2010, states: "EPA has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes. These comments are related to the conceptual site model (Linking Sources to In-Water Contamination), the data lockdown date, and the inclusion of the PBDE fish tissue data in the BHHRA. EPA has determined that these comments must be addressed to complete the RI and BRA Reports, and hereby directs the LWG to revise the draft RI and BRA Reports as described in Attachment 1. . . . **Because we did not discuss all of the comments or details on how the individual comments will be addressed, a final determination that the LWG has addressed the directed and non-directed comments can not be made until redline-strikeout versions of the RI and BRA Reports are submitted (emphasis added).**"

EPA's actions and decisions regarding the draft BHHRA have all been in accordance with the review and approval process set forth in the AOC that the Respondents agreed to and which is the operative document that provides the process and roles and responsibilities of EPA and the signatories. The Respondents characterize EPA's modification of their second draft BHHRA as "a defining moment" that will have "ramifications far beyond the document itself." Opening Statement page 2. Although we can't refute that they may have these feelings, given the clear language of the AOC and the review and approval process set forth therein, there is no reasonable basis in law or fact that supports Respondents' arguments that EPA acted arbitrarily or capriciously in modifying the BHHRA. There too is no reason for the AOC to be amended to add a "set of documented protocols to guide better working relationship between the [Respondents] and EPA...." Opening Statement page 3.

EPA acknowledges the significant work and effort that Respondents have put forth to get the RI and FS to where it is today. We want to emphasize to the Director and to the other potentially responsible parties who will be asked to participate in the remediation of the Portland Harbor Superfund Site that EPA's modifications were to the text of BHRRA. EPA had no problems nor did we change the calculations or analysis that made up the majority of the work and effort doing the risk assessment. In fact, most of the Respondents' words were retained by EPA, but moved to other locations and/or redundancies eliminated. EPA's modifications to the text were made, as we have stated numerous times, to make the document more clear, transparent, and consistent with EPA guidance. Given the importance of this analysis and its role in future remedy decisions, it is imperative that the document be clear as possible regarding the major assumptions and conclusions. That is not to say, however, that the entire risk assessment process undertaken by Respondents was inadequate. We have never said it was. Anyone who reads the back and forth on this dispute must conclude that EPA's modifications to the BHHRA did not change, revise, or eliminate the majority of Respondents' work on the human health risk assessment.

The EPA took two separate actions related to the Respondents' second draft BHHRA. First, as early as July 2011, EPA decided to modify the second draft BHHRA in order to have an approvable final BHHRA as quickly as possible, *see* Tabs 18 and 19.[6] On June 22, 2012, EPA provided the modified BHHRA to the Respondents and took its second action, which was to

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[6] EPA's letter to Respondents, dated July 21, 2011, notified them that "EPA has the right to modify any deliverables under the AOC, which EPA intends to do with the BHHRA. Consequently, EPA is requesting all the original document (Word, Excel, etc.) files used to create the BHHRA so that we can modify the document." EPA's email to LWG, dated July 22, 2011 further clarified that "EPA believes that there are changes needed to some of the language and presentations in the document, and it will be most efficient for EPA to mark up the document with those specific changes rather than provide additional comments that would then lead to further back and forth (comment & revision cycles) between EPA and LWG. The intent is to expedite the process by providing an approvable red-lined document that the LWG could then finalize."

notify the Respondents' that their second draft was inadequate and did not fully reflect EPA's directions for changes in compliance with the notice requirements of Section XIX., Paragraph 1 of the AOC. EPA's second action began the accrual of stipulated penalties, but EPA has not assessed penalties yet. The two actions are separate and distinct. EPA has the authority to comment on, modify, and direct changes to any deliverable whether or not the Respondents are determined to be violation of the AOC. Likewise, EPA may determine that Respondents have not complied with the AOC but does not have to modify the offending document. In this dispute, the Respondents dispute both EPA's noncompliance determination and a few technical issues related to the modified BHHRA. They also dispute the process EPA used in taking its actions.

EPA will respond to the specific issues raised by Respondents in the remainder of this response document. Based on our responses and the administrative record created for this dispute, EPA respectively requests the Director to make the following decisions:

1. Uphold EPA's determination under the AOC that Respondents failed to produce a deliverable of acceptable quality, or otherwise failed to perform in accordance with the requirements of the AOC because they did not adequately address all of EPA's comments;
2. Adopt EPA's positions, as presented in this response, on the appropriate Reasonable Maximum Exposure and Central Tendency Exposure Scenarios for recreational and subsistence fishers for incorporation, as appropriate, into the text and tables and figures of the final BHHRA;
3. Agree with EPA's positions on exposure scenario and uncertainty language regarding domestic water and clam consumption (which would require no additional changes to the draft BHHRA text);
4. Agree with EPA's positions regarding the Executive Summary, Table of Contents, and Conclusion sections;
5. Adopt the revised BHHRA, dated September 17, 2012, [Respondents' Exhibit 1 and EPA's Exhibit 13] which incorporates a majority of the resolutions reached between Respondents and EPA as of September 14, 2012, and require that the resolutions of the disputed technical issues (2, 3, and 4, above) from this dispute will be incorporated, if necessary, by EPA into the final document[7]; and
6. Determine that the Respondents' request to establish protocols for better working relationships would be an amendment to the review and approval process and

[7] EPA agrees that substantial progress was made during the informal dispute process and that Tables 1 and 2 generally reflect the specific issues raised by Respondents that they and EPA reached some form of resolution on. But it is only the specific agreed-upon language reflected in the red-lined text of the Sept 17, 2012 BHHRA that has been agreed to so far. Thus, EPA does not believe it is necessary or appropriate for the Director to approve Tables 1 and 2 themselves.

enforcement provisions of the AOC and, thus, is not relief that can be addressed through the dispute resolution process.

II. EPA'S MODIFICATION OF THE RESPONDENTS' SECOND DRAFT BHHRA COMPLIED WITH THE AOC REVIEW AND APPROVAL PROCESS.

Since the AOC is the controlling document for judging the process and circumstances surrounding EPA's modification of the BHRRA and noncompliance determination, it is important to highlight the most relevant provisions contained in it. By signing the AOC, the Respondents agreed to the process put forth in the AOC. EPA will describe below how it used and complied with the process prescribed in the AOC with respect to the BHHRA deliverable.

Section II, Paragraph 2, of the AOC states:

> "Respondents agree to undertake all actions required by this Consent Order. In any action by EPA or the United States to enforce this Consent Order, Respondents consent to and agree not to contest the authority or jurisdiction of EPA to issue or enforce this Consent Order, and agree not to contest the validity of this Order."

Section IX, Paragraph 1, of the AOC states:

> "EPA reserves the right to comment on, modify, and direct changes for all deliverables in writing . . . EPA will meet with the Respondents in an effort to resolve disputes. At EPA's discretion, Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables within a time frame specified by EPA."

Section XIX., Paragraph 1, of the AOC provides:

> ". . . for each day that Respondents fail to complete a deliverable in a timely manner or fail to produce a deliverable of acceptable quality, or otherwise fail to perform in accordance with the requirements of this Order, Respondents shall be liable for stipulated penalties. . . .Where a revised submission by Respondents is required, stipulated penalties shall continue to accrue until a satisfactory deliverable is produced. EPA will provide written notice for violations that are not based on timeliness; nevertheless, penalties shall accrue from the day a violation commences."

The Respondents were required to produce a Baseline Human Health Risk Assessment as a deliverable under the AOC and SOW to be approved by EPA, *see* AOC Section VIII and Task 5 of the SOW, Section 7.8.3. The Respondents provided a draft final BHHRA on May 2, 2011, after significant commenting occurred on its first 2009 draft and several meetings were conducted on those comments, as discussed above.

As plainly reserved in the AOC, the EPA chose to modify this version of the BHHRA to fix the readability and objectivity of the document and better justify the basis for specific assumptions used in the BHHRA.[8] The EPA also modified the document to include an RME for recreational fishers and subsistence fishers to comply with CERCLA's mandate that remedial actions be protective of human health and the environment[9] and be consistent with EPA guidance.[10] In a letter dated July 21, 2011, and in a follow-up email on July 22, 2011 (*see* Tabs 18 and 19), EPA notified the Respondents of its intent to modify the BHHRA document, although notice is not required by the AOC.

Also consistent with the AOC, EPA found that there were at least 17 comments that were not adequately addressed as required by the AOC and notified the Respondents in its June 22, 2012 letter that they were out of compliance with the AOC. The AOC provides that stipulated penalties begin to accrue from the date of noncompliance until compliance is achieved and EPA's noncompliance notice merely reiterated what the AOC says.

The Respondents contend EPA was arbitrary and capricious in finding them out of compliance and claim we did so to coerce them to accept our modifications. The EPA was not being coercive, but rather utilizing the enforcement options that are clearly laid out in the AOC to achieve a final BHHRA as soon as possible. Penalties accrue until a satisfactory document is produced so there is an incentive for parties to complete documents expeditiously. Furthermore, Section XIX, Paragraph 1, also provides that in determining whether to waive imposition of penalties EPA can consider the Respondents' good faith attempts to comply or timely correction of defects. The Respondents were fully aware of EPA's discretion in this area, and now cannot cast EPA as being coercive in using its enforcement authorities to achieve a satisfactory, final document.

Section IX, Paragraph 1, of the AOC states that "EPA will meet with Respondents in an effort to resolve disputes." In EPA's June 22, 2012, letter, *see* Tab 16, EPA project managers offered to coordinate and discuss questions the Respondents had with the required changes to the BHHRA. On July 17, 2012, at the request of Bob Wyatt and Jim McKenna, EPA staff, Chip Humphrey, Kristine Koch, and Elizabeth Allen, had a conference call to discuss the modified BHHRA. During that call, the Respondents indicated that they were "not trying to resolve anything" and "wanted to talk about LWG's reactions" to the BHHRA comments. They requested EPA do two things or they would dispute the changes: 1) retract the determination of noncompliance; and 2)

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[8] A consistent comment EPA gave to Respondents' starting with comments on their Round 2 characterization report was that discussions of risk needed to be objective and unbiased. *See* Exhibits 10 and 11.

[9] 42 U.S.C. § 9621(b)(1) and 40 CFR §§300.430(a)(i) and (e)(9)(iii)(A).

[10] EPA/540/1-89/002, OSWER Directive 9355.0-30, OSWER Directive: 9285.6-03, OSWER Publication 9285.7-081, EPA/600/P-95/002Fa-c, EPA 823-B-97-009, EPA-821-R-00-025, EPA 823-B-00-007, EPA-822-B-00-004, Office of Emergency and Remedial Response, Publication 9285.7-47, EPA 540-R-02-002, OSWER 9285.6-10, EPA 821-C-02-003, OSWER Directive 9285.7-53, EPA/630/R-03/003F, and EPA/600/R-09/052F (other relevant guidance is cited in the reference section of the BHHRA).

retract the directive changes to the BHHRA. They also stated that further discussions would not stop the Respondents from disputing the required changes. Since EPA was not willing to retract the directive changes to the BHHRA, the Respondents chose to invoke dispute resolution in accordance with Section XVIII of the AOC on July 23, 2012. Between July 23, 2012, and September 14, 2012, the Respondents and EPA had several meetings in an attempt to informally resolve the Respondents' dispute issues, *see* Tables 1 and 2, and were successful in resolving all but the three technical issues the Respondents raises in this formal dispute.

III. RESPONDENTS DID NOT COMPLY WITH THE AOC BECAUSE THEY DID NOT FULLY CORRECT ALL DEFICIENCES AND INCORPORATE ALL COMMENTS SUPPLIED BY EPA.

On June 22, 2012, EPA notified the Respondents that they failed to produce a BHHRA of acceptable quality, or otherwise failed to perform in accordance with the requirements of the Order by failing to fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA on prior versions of the BHHRA, *see* Tab 16. On July 17, 2012, Respondents' representatives and EPA staff had a conference where Respondents requested EPA do two things or they would dispute the changes: 1) retract the determination of noncompliance; and 2) retract the directive changes to the BHHRA. Since EPA was not willing to retract the directive changes to the BHHRA, the Respondents chose to invoke dispute resolution in accordance with Section XVIII of the AOC on July 23, 2012(*see* Tab 21). Consequently, EPA provided the Respondents with the basis for noncompliance on July 27, 2012 (*see* Tab 22), since that would be part of their dispute.

In EPA's review of the draft final BHHRA, EPA determined that several of its comments were not adequately addressed or incorporated into the document. Section IX, Paragraph 1, of the AOC states that "At EPA's discretion, Respondents must fully **correct all deficiencies and incorporate and integrate all information and comments supplied by EPA** either in subsequent or resubmitted deliverables within a time frame specified by EPA." (emphasis added). The EPA clearly stated in its transmittal of comments in July 2010 on the BHHRA (*see* Tab 7) its direction that "EPA expects the LWG to address all of the comments." EPA further repeated this direction in its letter on December 8, 2010 (*see* Tab 12) in stating "[h]owever, EPA believes that addressing all directed comments and non-directed comments consistent with previous direction and agreements, and the direction and clarifications in this letter and attachment, should resolve EPA's RI and BRA Report comments."

The EPA agrees that it is our initial burden to prove a violation of the AOC. However, the AOC sets a very, strict standard for the Respondents, i.e., "correct all deficiencies and incorporate and integrate all information and comments supplied by EPA . . . ." Thus, by its express terms, if just one comment is not addressed, the Respondents have not complied with Section IX., Paragraph 1 of the AOC, and stipulated penalties begin to accrue until the deficiency is corrected. In this case, the EPA identified 17 comments and/or issues that the Respondents did not address

adequately. Attached as Exhibit 6 to this Response is EPA's detailed recitation of the EPA's rationale for why these comments were not fully incorporated or addressed in the draft final BHHRA with additional discussion responding to Respondents' arguments. We believe that the information contained in Exhibit 6 meets our burden for proving that the Respondents did not comply with the AOC.

The Respondents argue that only directed comments versus non-directed comments[11] can be a matter for noncompliance. But such limitation or qualification is found nowhere in the AOC itself, and in fact, would directly contravene Paragraph 1 of Section IX that requires all deficiencies and comments to be addressed. To support their position, the Respondents culled the phrase "EPA's directions for changes" from Paragraph 4 of Section IX.,[12] which speaks to what actions or enforcement options EPA has if it disapproves a revised report or if subsequent submittals do not fully "reflect EPA's directions for changes." However, it is not reasonable to read that paragraph as limiting EPA enforcement to only directed changes, because it is inconsistent with other provisions of the AOC, particularly, Paragraph 1 of the same Section. Rather, the phrase, "directions for changes", in Paragraph 4 logically must be read as an abbreviated restatement of "**correct all deficiencies and incorporate and integrate all information and comments supplied by EPA"** found in Paragraph 1. The EPA clearly stated in its transmittal of comments in July 2010 on the BHHRA (*see* Tab 7) and in its letter on December 8, 2010 (*see* Tab 12) that its direction was that EPA expected the Respondents to address all of the comments provided by the EPA. Additionally, Section XIX. of the AOC regarding stipulated penalties contains no language that limits EPA's enforcement authority to a particular type of comment, such as only directed comments.

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[11] The AOC does not define or provide for directed comments versus non-directed comments explicitly. The process of reviewing deliverables that has developed between EPA and Respondents over time has led to more specific descriptors provided by EPA to its comments, such as "clarifying comments" or "directed changes." Likewise, resolving disagreements over comments and directed changes included frequent meetings between EPA and LWG technical staff and project managers. For major deliverables, the process often involved use of comment resolution tables to track, and narrow the list of disagreements. In many cases, agreements were reached through the comment resolution process, the Respondents modified the documents in accordance with EPA's comments and direction, and documents were subsequently approved. When it became apparent that agreements on certain issues could not be reached, EPA would direct the Respondents to make the changes or Respondents would request EPA to direct them so they could reserve their disagreement. EPA typically was more "directive" in requiring changes after allowing the Respondents the opportunity, or in some cases multiple opportunities, to modify unacceptable documents to correct deficiencies.

[12] Section IX, Paragraph 4 of the AOC states that "If LWG amend or revise a report, plan, or other submittal in response to EPA comments, and EPA subsequently disapproves of the revised submittal, or if such subsequent submittals do not fully reflect EPA's directions for changes, EPA retains the right to seek penalties, perform its own studies, complete the RI/FS (or any portion of the RI/FS) under CERCLA and the NCP, and seek reimbursement from LWG for costs, and/or seek any other appropriate relief."

The fact that this is the first time the EPA has made the determination of noncompliance is irrelevant to whether the Respondents failed to address all comments on the draft BHHRA. The EPA's decision not to take an enforcement action previously does not raise the standard of what is a violation of the AOC nor can it be deemed a waiver of our right to bring a future enforcement action. In addition, the AOC provides EPA with enforcement discretion in determining whether or not Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA in a revised deliverable or in another future document (Section IX, Paragraph 1) and to whether or not to waive imposition of penalties considering the Respondents' good faith attempts to comply or timely correction of defects (Section XIX, Paragraph 1).

The record (*see* Exhibit 6) is clear that the Respondents' second draft BHHRA did not address "all deficiencies and incorporate and integrate all information and comments supplied by EPA" and thus, is in violation of the AOC. If the Director finds that EPA has proven that one or more comments or direction for change was not adequately addressed or incorporated, then, by the terms of the AOC, the Respondents are in noncompliance. However, in the future, when the BHHRA is finalized, agency discretion may be applied in determining whether to assess stipulated penalties and, if so, whether to assess an amount less than the full stipulated amount.

IV. EPA'S TECHNICAL POSITIONS ON THE BHHRA ARE SCIENTIFICALLY JUSTIFIED AND CONSISTENT WITH CERCLA, THE NCP, AND EPA GUIDANCE

A. EPA's positions on the Reasonable Maximum Exposure for recreational and subsistence fishers are reasonable and appropriate for the Portland Harbor Superfund Site and consistent with EPA guidance. It is not necessary to further delay the RI/FS schedule to engage in more discussions regarding the RME for these receptors.

1. History of RME and CT Discussion between EPA and Respondents.

Beginning in at least 2003, EPA and Respondents had extensive discussion on the fish consumption rates as well as other variables for the risk assessment. The consumption rates to be used in the risk assessment were established as far back as 2004. The Respondents want to go back to square one on many of these issues. However, there is substantial support in the record for maintaining the consumption rates used in the risk assessment and determining the RME and CT for recreational and subsistence fishers.

Respondents provided a draft Programmatic Work Plan on March 31, 2003, and subsequently submitted proposed fish consumption rates for the Portland Harbor human health risk assessment on May 9, 2003 (*see* Tab 26). The EPA provided comments on the draft Programmatic Work Plan on July 25, 2003 (*see* Tab 33). In that letter, EPA noted that comments on the May 9, 2003 proposed fish

consumption rates would be provided at a later date, but stated that there were significant issues with Respondents' RME for fish consumption.

Respondents requested a schedule extension on the Programmatic Work Plan on October 15, 2003 (Exhibit 7) and subsequently provided a draft final Programmatic Work Plan to EPA on November 10, 2003, Exhibit 8. On February 11, 2004 (*see* Tab 27), EPA further commented on the Programmatic Work Plan and provided direction on fish consumption rates. On February 23, 2004, the Respondents sent a letter (Exhibit 9) which indicates that a meeting was to be held on March 3, 2004, and that fish consumption rates were to be discussed.

EPA sent a conditional approval letter to the Respondents on March 15, 2004, (*see* Tab 47). In the letter, Condition 3 (Text changes to the RI/FS Work Plan) specified that the included text changes were based on review of the February 27, 2004, and March 5, 2004, redline versions of the Work Plan, discussion and agreements during the March 3, 2004 meeting, and subsequent discussions between the EPA and the Respondents. Specific comments on fish consumption rates were provided in the comments for Appendix C, Section 3.4.3. It was clear at this point that both parties agreed that consumption rates would not be designated as representing either RME or CT exposures and that a range of consumption patterns for fishers using the ingestion rates of 17.5 g/day, 73 g/day, and 142 g/day would be used for adult consumption. These consumption rates were anticipated to represent average to high end ranges of fish consumption for the recreational and subsistence fishers.

As the record shows, there was significant debate and disagreement regarding fish consumption rates and even what to name the various fisher categories. To keep the process moving forward, EPA agreed that Respondents did not have to identify RME for the fisher receptors in their drafts of the BHHRA.

2. Basis for EPA Determining that the BHHRA Needed to be Modified to Include an RME for Recreational and Subsistence Fish Consumption.

Both the NCP and EPA guidance are clear that the risk assessment should present an assessment of reasonable maximum exposure. The preamble to the NCP states that "In the Superfund program, the exposure assessment involves developing reasonable maximum estimates of exposure for both current land use and potential future land use conditions,[13]" while RAGS Part A notes that "actions at

[13] 55 Fed Reg. 8666 at 8710 (*see* Tab 30).

Superfund sites should be based on an estimate of the reasonable maximum exposure expected to occur under both current and future land-use conditions."[14]

Therefore, to be consistent with both national policy and EPA's human health risk assessment guidance and to have a clear and transparent record to establish that the selected remedy is protective of human health, an RME for recreational and subsistence fishers needs to be identified. EPA's modifications to the BHHRA did so.

EPA's modified version of the BHHRA (*see* Tab 16) utilized the Respondents' calculations to the greatest possible extent while meeting the intent of our February 2004 direction on fish consumption which clearly noted that the 17.5 g/day represented a central tendency value, and that 73 g/day and 142 g/day represented higher end (~95th percentile) consumption rates for the recreational fisher and the non-tribal high fish consumers, respectively. Semantics aside, these descriptions clearly fit the definitions of CT and RME.

3. EPA's Definition of RME is Consistent with Guidance and National policy.

The Respondents claim that it is inconsistent with guidance and national policy to designate a specific ingestion rate as the RME versus the overall exposure pathway. However, there is nothing in EPA guidance or policy to support the conclusion that RME must be defined only as a pathway. As noted, EPA's June 22, 2012, redlined BHHRA (*see* Tab 16) made a distinction that for different receptors (recreational versus subsistence fishers) different consumption rates represented CT and RME variables for contact rate. RAGS Part A (Section 6.4.1) provides that when evaluating RME, both the contact rate and exposure frequency and duration should approximate 95th percentile or upper-bound values. Thus, the designation of specific consumption rates as representing RME values is not the same as stating that the intake alone represents RME, but rather the consumption rates represent specific components of an overall assessment of RME.

EPA's June 22, 2012 redlined BHHRA (*see* Tab 16) deleted the evaluations of fish consumption which used the simple arithmetic mean as the exposure concentration. This is consistent with EPA guidance[15] which defines the exposure concentration as a central tendency value represented by the 95 percent upper confidence limit on the arithmetic mean. Also consistent with EPA guidance, upper-bound (95th percentile) values were used to represent exposure duration

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[14] RAGS Part A Section 6.1.2 p. 6-4, (*see* Tab 29)
[15] RAGS Part A Section 6.4.1 p. 6-19 (see Tab 29)

(since consumption rates are presented as long-term averages as g/day, the exposure frequency is inherent in the contact rate). Thus, EPA's designation of RME fish consumption scenarios in the June 22, 2012 revised BHHRA are consistent with guidance.

Further, the argument that exposure should not be evaluated on spatial scales smaller than the defined site boundaries has no rational basis. EPA guidance is clear that exposures should be evaluated based both on the chemical distribution at the site, and the location and activity patterns of the potentially exposed populations. Ample precedence is available from other Superfund risk assessments that evaluate RME on the basis of operable units or distinct sources and areas of contamination, rather than on an overall site-wide basis.

During the informal dispute process, discussions on the RME occurred and EPA agrees some adjustments to its original RME for recreational and subsistence fishers is appropriate. The Respondents provided a RME proposal on August 29, 2012 (presented herein as Exhibit 16), EPA presented its revised RME proposal to the Respondents on September 11, 2012 (included herein as Exhibit 17), but Respondents dispute our proposal and have requested to have further discussions on the issue. Both proposals utilized the information currently existing in the BHHRA rather than requiring a re-evaluation of exposure values. We maintain that these issues have been debated for over ten years and there is sufficient information to support EPA's RME proposals and finalize the BHHRA. The Director should find that the current RME proposal is adequate for the Portland Harbor BHHRA and should be incorporated into the final BHHRA.

4. Significant Components of EPA's Recreational and Subsistence RME Proposal for Incorporation into the Final BHHRA.

Summarized below, the significant components of EPA's proposed RME for recreational and subsistence fishers are as follows:

EPA has identified two different non-tribal receptor populations, recreational and subsistence (or high-consuming) fishers, distinguished primarily on consumption rates and practices. This is acknowledged in the Programmatic Work Plan, *see* Tab 1. Consistent with other exposures evaluated in the BHHRA, recreational fishers will be evaluated for both CT and RME. Subsistence fishers are evaluated for RME only, because central tendency exposures for this high-consuming population are adequately described by the RME evaluation for recreational fishers.

Fish Tissue Consumed: Recreational fishers will be based on consumption of fillet with skin, which is consistent with the results of numerous fish consumption

surveys indicating that recreational sport fishers primarily consume only the fillet portion of the fish. This is also consistent with the existing data for Portland Harbor, which includes contaminant concentrations in the fillet. Subsistence fishers will be evaluated assuming both fillet with skin consumption, as well as whole body. Assuming whole body consumption accounts for the varying consumption practices among the various cultures that supplement their diet by fishing, and for different preparation techniques, which include consumption of other parts of the fish including the head, or using the whole fish to prepare soups. EPA acknowledges that consumption of the entire fish may not represent a common practice, but that the degree to which whole body data may overestimate intake should be assessed as an uncertainty. This is consistent with RAGs Part A, Section 4.5.6.

Species Consumed: Both recreational and subsistence fishers are assumed to consume a multi-species diet, consisting of resident fish. An evaluation of the risks associated with migratory fish is not informative as to the risks associated with contamination within Portland Harbor. The multi-species diet of resident fish will be evaluated using the existing fish tissue data and assuming equal proportions of the four resident fish for which data are available.

Exposure Area: Recreational fishers will be evaluated on both a harbor-wide scale and on a smaller exposure area approximating each river mile. Harbor-wide exposures will provide a more generalized assessment of the risks associated with fish consumption at Portland Harbor; however, an assessment on a river-mile basis will inform the risks associated with the heterogeneous contaminant distribution in sediment reflecting distinct sources and associated release areas and the fact that most fishers are unlikely to uniformly fish throughout the entire 10-mile long site. Further, many fishers likely repeatedly frequent the same area either from habit, past fishing success, or accessibility. Not all fishers have access to all areas of the river through the use of boats, and some may rely on public transportation and primarily access areas located closest to bus lines.

In order to utilize the existing results to the greatest possible extent, EPA proposes using the data from Smallmouth bass as a surrogate for a multi-species diet assessed per river mile. Smallmouth bass represent the only species for which tissue data is available by river mile. Of the four resident species for which tissue data are available, measured contaminant concentrations are generally greater in Common carp and Brown bullhead, and less in Black crappie. Thus, Smallmouth bass present an appropriate means to assess risks associated with fish consumption by river mile.

Fish Consumption Rates: The technical justification for the consumption rates for both recreational and subsistence fishers is well documented in Section 3.5.10.6 of the Sept 17, 2012 BHHRA. As proposed by the Respondents during the informal dispute, *see* Exhibit A, the use of 17.5 g/day as a RME estimate for recreational consumers is unsupported. As noted in Section 3.5.10.6 of the BHHRA, the rate of 17.5 g/day is representative of the general U.S. population and not that portion that regularly consumes fish. The corresponding 90th percent consumption rate for consumers only is 200 g/day. EPA's Ambient Water Quality Guidance describes 17.5 g/day as an "average" consumption rate for recreational sport fishers. The use of this value rather than the corresponding 200 g/day rate accounts for the likelihood that recreational fishers consume more than just resident fish, and that not all fish consumed are caught within Portland Harbor. EPA acknowledges that the national consumption include shellfish, which account for as much as 40 percent of the overall consumption rates. However, given that the range between 17.5 g/day and 200 g/day is quite large, and the precise consumption of locally-caught fish by recreational fishers at Portland Harbor either currently or in the future is unknown, the assumption of 17.5 g/day as a central tendency estimate is reasonable and within the plausible range of uncertainty.

EPA also acknowledges the limitations and technical issues associated with the rate of 73 g/day from the Columbia Slough survey as representing a RME consumption rate for recreational fishers. The Columbia Slough survey was clearly a survey of fishers, but does not designate whether the fishers were recreational or subsistence. EPA disagrees with the Respondents' conclusions that this study is of subsistence fishers because of the apparent ethnic background of those surveyed. However, use of this survey falls within the recommended hierarchy of giving preference to surveys conducted within the local area or region (*see* Tab 42). Assuming fillet-only consumption and that 30 percent of the total weight of the fish is consumed, the corresponding rate is 29 g/day. This value is approximately within a factor of 2 of the 73 g/day value proposed by EPA. Thus, any revisions using a lower consumption rate than the 73 g/day as proposed would have minimal effect on the corresponding risk estimates for recreational fishers.

5. EPA's Proposed RME is Well Defined and Further Discussions are not Warranted and Would Only Delay Progress.

There is no basis to further delay the Portland Harbor project to conduct yet another review of the same "available guidance, fish consumption surveys from other freshwater systems and other Superfund sites to determine a recommended fish consumption rate." These issues were discussed for two years during the

Programmatic Work Plan development. The Respondents have not presented any new information that shows the fish consumption rates are unreasonable for the Portland Harbor Superfund Site. Also, contrary to Respondents' premise, EPA has tracked new studies and information issued over the years that might inform the risk assessment for Portland Harbor and find nothing leads us away from these rates but rather further supports their reasonableness.

EPA's Exposure Factors Program regularly conducts exhaustive reviews of the available literature to establish recommended exposure factors. As described in Chapter 10 of the 2011 Exposure Factors Handbook (Exhibit 19), only a single survey of freshwater recreational anglers was found from the Pacific Northwest (*see* Table 10-5 of Exhibit 19). The 95th percentile consumption rate was 42 g/day for recreational fishers in Lake Sammamish, Lake Washington, and Lake Union. A Washington Dept of Ecology Technical review (*see* Exhibit 20) of fish consumption rates for marine recreational fishers in King County revealed 95th percentile consumption rates from 42 g/day to 221 g/day. A statistical analysis of the national consumption rates presented in the Centers for Disease Control's 2003-2006 National Health and Nutrition Examination Survey (NHANES) designed to account for the relatively short reporting period reports the 90th and 99th percentile consumption values of finfish for consumers only as 115 g/day and 217 g/day. *see* Exhibit 18. An additional evaluation based on the rate of licensing in Washington as an estimate of locally harvest fish provides consumption rates of finfish at 43 g/day at the 95th percentile and 72 g/day at the 99th percentile.

As can be determined, EPA's recommended CT and RME consumption rates for recreational fishers are within the plausible range of reasonable consumption rates for a water body the size of the Lower Willamette River, and any reassessment of the available literature will not result in an appreciable change to the overall consumption rates, and thus the overall assessment and the conclusions of the assessment. Given the uncertain knowledge of actual consumption practices in Portland Harbor, the rates currently used in the BHHRA are within any plausible range of uncertainty, and further re-evaluations and calculations would only yield similar results.

As with the consumption rates used to represent recreational fishers, the recommended consumption rate of 142 g/day for high-consuming, or subsistence fishers is well within the range of plausible values. As noted in EPA's guidance for Ambient Water Quality Criteria (Tab 42), 142 g/day is considered an average consumption rate for non-tribal subsistence fishers, and the corresponding adjusted 99th percentile consumption rate for finfish (consumers only) is 217 g/day and 72 g/day for locally-harvested fish (Exhibit 18). Hence, using a rate of

142 g/day accounts for the myriad of uncertainties associated with actual consumption rates for Portland Harbor, including the amount of resident fish consumed. Any reevaluation of risk assuming slightly different consumption rates would not yield notably different results.

B. EPA's revised BHHRA text on exposure assessment, risk characterization, and uncertainty sections of the BHHRA regarding the drinking water scenario and clam consumption scenario is reasonable and appropriate for the Portland Harbor Superfund Site and is consistent with the NCP and EPA guidance.

The Respondents dispute EPA's June 2012 directed redline that deleted relevant context information for the domestic water use and clam consumption scenarios from everywhere they claim it should be stated in the BHHRA. Please note that relative to the context information at issue, EPA did not delete the language entirely from the June 2012 modified risk assessment; the language is retained in the uncertainty section (Section 6) of the BHHRA. The Respondents acknowledge that the September 17, 2012 draft contains some of the context information they want, but not all.

The Respondents assert that critical information is lacking from the Exposure Assessment Discussion in Section 3 at 3.2.1.8 by noting that the September 17, 2012 redline would "direct the LWG to include the following in the description of the domestic drinking water exposure scenario in Section 3.2.1.8:

> Although there are currently no known uses of the Lower Willamette River as a source of drinking water, public and private use of the Willamette River as a domestic water source is a designated beneficial use by the State of Oregon. Hence, use of surface water as a source of household water was assessed as a potentially complete pathway."

The Respondents assert the information is inaccurate by omission in that it infers that water will be used untreated because State rules require pretreatment. No reasonable reader could make this inference because Section 1 of the BHHRA, page 25 of the September 17, 2012, version, explains that a baseline risk assessment should evaluate human health risks associated with contamination in the absence of remedial actions or institutional controls (such as State pretreatment requirements). Additionally, Section 3.2, page 44 of the September 2012 version, states specifically in relation to the private or public use of surface water as a drinking water source that "this baseline risk assessment evaluates exposures assuming no institutional controls, such as obtaining a permit for use of surface water."

Oregon's water quality standards for the Lower Willamette River establish that domestic water supply is a designated use, thus, the lower Willamette River is to be protected for such use from point and non-point sources. The Respondents are focused on a notation in

Oregon's water quality standards that indicates that adequate pretreatment is assumed relative to the designated use of domestic water supply, and contend that notation must have some legal significance such that the exposure assessment description in Section 3.2.1.8 is inaccurate without mentioning it. Attached as Exhibit 14 is a copy of the excerpt from Oregon's promulgated water quality standards. First, the Oregon water quality standards are not independently enforceable, thus the notation itself certainly is not. An NPDES permit, water quality certification or other type of license issued by Oregon's Department of Environmental Quality is required to enforce water quality standards. Secondly, following Respondents' logic, every other regulation for purveyors of drinking water in the State of Oregon would also need to be mentioned in Section 3.2.1.8, such as the Oregon Health Authority's administrative rules for public water supplies found at OAR 333-061-005. There likely are other rules and regulations that would relate to the use of surface water as a drinking water supply. However, the point is that a baseline risk assessment assesses risk assuming the receptor is exposed to the surface water and contamination in such surface water in absence of any regulation.

Following this same logic, EPA believes there is no statement "inaccurate by omission" in Section 3.3.6 regarding consumption of shellfish, including Asian clams because it fails to note that harvesting Asian clams is prohibited by State law. By definition, the baseline risk assessment assesses this exposure pathway assuming no existing institutional controls.

Let's be clear, the Respondents and EPA only disagree about where the discussion of a couple of Oregon Statutes should be presented in the BHHRA, not the omission of said language entirely. EPA modified the text of the draft BHHRA to make the document clear, transparent, and defensible. We believe we achieved that goal. We have agreed to make reasonable changes that Respondents have requested, while maintaining the clarity we sought to obtain. EPA's position on this issue should be upheld.

1. EPA's modifications are consistent with guidance.

Nowhere in Section 5.3.3 of the Exposure Assessment Guidelines is "context" discussed. This section notes that exposure assessments can be used to assess the impact of possible control actions by changing the assumptions to represent conditions that would exist after the action is implemented and reassessing the exposure and risk. However, such an evaluation in a baseline assessment would be inconsistent with EPA's stated definition of a "baseline" risk assessment. RAGS Part A defines a baseline assessment as "an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action)" (*see* Tab 1, RAGS Part A, Pages 1-4) It also states that the exposure assessment should consider the general physical

characteristics of the site and characteristics of the population that may influence exposure, such as location relative to the site, activity patterns, and the presence of sensitive subpopulations. The Respondents assert that it is "important to provide the RPM or risk manger with information related to the likelihood that the assumed conditions will occur to allow interpretation of a conditional risk estimate in the proper context." (Opening statement, p 26). However, their cited text from RAGS Part A is from Section 8.4, Assessment and Presentation of Uncertainties. More specifically, it is found in Section 8.4.1, which discusses presentation of site-specific uncertainties, including those associated with the definition of the physical setting. Accordingly, EPA believes that presenting this relevant information in the uncertainty section is entirely consistent with guidance, rather than contrary to EPA guidance as the Respondents assert.

The Respondents claim the risk assessment for the Lower Fox River (*see* Tab 44) excludes the domestic drinking water entirely because the Lower Fox River is not used as a primary drinking water source. Yet, contrary to this assertion, the risk assessment notes at 3861 (p 5-5) that the receptors evaluated includes "drinking water users," and at 3863 (p 5-7) that "Drinking water users are individuals that use water taken directly from the Lower Fox River as a source of drinking water." A detailed description of the process used to evaluate exposure via ingestion, dermal contact, and inhalation due to use of surface water as a source of drinking water and other household water source is provided at 3871-3874 (pp 5-15 to 5-18).

In a similar vein, there is nothing in guidance or policy that compels EPA to include in Section 3.3.6 information noting that harvest of Asian clams is illegal. While Asian clams are now the predominant shellfish present, they are not the only species found, and the exposure assessment is clear in its intended purpose of an evaluation of the harvest and consumption of shellfish, including Asian clams, in the absence of any existing prohibitions. Indeed, information cited in the risk assessment and in other sources (see Exhibit 15) indicates that the existing prohibition regarding harvesting and possession of Asian clams is largely ineffectual.

As noted previously, EPA's interpretation of its guidance is that information relevant to other than baseline conditions is most appropriately discussed in the presentation of uncertainties, as clearly described in Section 8.4 of RAGS Part A (*see* Tab 1). The Respondents express concerns this information has been "moved back to the uncertainty section (Section 6). EPA has shown that guidance and policy clearly state that the uncertainty discussion is the appropriate place for this supplemental information in the BHHRA. EPA notes that, at several instances during the informal dispute meetings, EPA offered to allay some of the

Respondents' concerns by presenting the uncertainties information in each relevant section of the BHHRA, rather than as a stand-alone discussion of all uncertainties in Section 6, which was the Respondents' original format. We note that a section-by-section uncertainties format is consistent with the suggested outline for a baseline risk assessment report presented as Exhibit 9-1 in RAGS Part A (*see* Tab 1).

2. The EPA's interpretation of the RAGs Part A and of the meaning of an institutional control in the context of the BHHRA is appropriate relative to assessing baseline risks.

There is no definition or discussion in RAGs Part A of the meaning of institutional controls. Additionally, there is no definition of institutional controls in CERCLA or the NCP.[16]

Risk assessments and risk assessment guidance relate to a scientific assessment of risk from exposure to contamination prior to any determination that remedial action is necessary. Thus, the perspective on what an institutional control is for purposes of a risk assessment is not necessarily the same as what an institutional control is as a component of a remedial action. Some controls that may be relevant to a particular exposure scenario may later become institutional controls used to implement a remedy, but many other types of controls may not be appropriate as a remedy component, such as Oregon laws requiring water purveyors to do pretreatment.[17]

C. A brief, concise executive summary consistent with the Formal Dispute Decision is appropriate for the final BHHRA, but not a separate conclusion section; the EPA always intended for there to be a Table of Contents.

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[16] The NCP discusses institutional controls and program management expectations, but does not define the term. *See* NCP 300.430(a)(1)(iii)(D).

[17] As a side note, it would be inconsistent with CERCLA if EPA were to agree that "pretreatment" of water from the Willamette River for domestic use includes treatment of hazardous substances released at the Portland Harbor Site and, thus, it's the purveyor of the water that should have to remediate the contaminants. CERCLA mandates that any remedial action attain Safe Drinking Water standards and water quality criteria established under the Clean Water Act. 42 U.S.C. §9621(d)(2)(A). Thus, the discussion of treatment is further irrelevant because the treatment that would occur absent releases of hazardous substances would typically be for bacteria, solids, and minerals (such as iron, manganese, and sulfur). If the discussion in the exposure assessment (Section 3) of the BHHRA includes such language as the Respondents request, the reader could misinterpret that there must be no risk from domestic water use since it will all be treated without CERCLA action, or that the PRPs would not be required to remediate any contaminants because the purveyor would be required to remove any objectionable contaminants.

The May 2, 2011, draft final BHHRA had a 17 page executive summary. Further, the BHHRA is an appendix to the Remedial Investigation report, which summarizes the BHHRA in Section 8. EPA determined that the executive summary was far too lengthy and redundant considering there was a similar summary in Section 8 of the RI report. However, EPA agrees that a more concise executive summary (on the order of three pages) that is consistent with the formal dispute decision would be appropriate for the final BHHRA. EPA notified the Respondents of this intent on September 14, 2011 (Exhibit 4).

EPA does not see a need to have both a Summary section and a Conclusions section in the BHHRA. The conclusions of the BHHRA are presented in the Summary (Section 7) of the document and EPA has determined that this discussion is sufficient. There is no need for two subsequent sections in the BHHRA that discusses the same information.

EPA had always intended for there to be a table of contents in the document and is unclear why the Respondents are now raising this issue. This issue was not raised during the informal dispute resolution discussions that took place between July and September. All versions of the document, including the latest version, *see* Respondents' Exhibit 1, have a placeholder for a table of contents. EPA removed the details of the table of contents from the document since the modifications being made to the document were playing havoc on the automatically updated table of contents, *see* Tab 16.

V. IT IS INAPPROPRIATE TO AMEND THE AOC THROUGH THE FORMAL DISPUTE PROCESS, BUT IF ITS DETERMINED TO BE APPROPRIATE RELIEF FOR THIS DISPUTE, THEN ON THE MERITS NO AMENDMENT TO THE AOC IS NECESSARY.

A. The Respondents are seeking to amend the terms of the AOC through the dispute process which is not the appropriate or relevant process.

"[T]he LWG requests that the ECL Director commit to meet with the LWG Senior Management and to establish a mutually-agreed upon set of documented protocols to guide a better working relationship . . . .:" page 33 of Opening Statement. We understand the Respondents dispute how EPA modified the BHRRA, but the relief they seek is not appropriate as a resolution to a dispute.

1. Amending the terms of the AOC is not within the scope of the dispute resolution process provided by the AOC.

Section XVIII. Paragraph 1 of the AOC provides: ". . . If Respondents object to any EPA notice of disapproval or requirement made pursuant to this Consent Order, Respondents shall notify the EPA Project Coordinator in writing . . . of their objection(s) . . . of the disapproval notice or requirement." Respondents can dispute how and why EPA modified its deliverable, but seeking a dispute decision agreeing to documented protocols to guide a future working relationships is an amendment to the AOC, not a resolution of a

"disapproval or requirement made" under the order. Nowhere in the dispute resolution provisions does it say the AOC can be amended through that process. That is because the AOC includes a specific amendment section, e.g., Section XXVII.

Section XXVII of the AOC provides that the way to amend the AOC is through a mutual agreement of EPA and the Respondents. Amendments shall be in writing and shall be effective when signed by EPA's delegated authority. Section XXVII does not reference Section XVII, the dispute resolution process, as an alternative means to amend the AOC, nor does it provide that any other process can be used to amend the AOC.

The dispute resolution process is not a consensus process such as required by an amendment to an agreement. Rather, it is an administrative dispute process at the end of which the Director of the Office of Environmental Cleanup ("ECL") makes the final decision. Section XVIII, Paragraph 1, clearly provides that the ECL Director's determination is EPA's final decision and the Respondents shall proceed in accordance with EPA's final decision regarding the matter in dispute, regardless of whether the Respondents agree with the decision. The Respondents' request that the ECL Director meet with the Senior Management to establish a documented set of protocols by its nature is not a dispute resolution issue, but rather an AOC amendment matter.

2. A meeting to discuss relationships and how to work better together is appropriate outside of the dispute process.

For all of the reasons stated above, the Director should determine that he cannot agree to meet and establish documented protocols on better working relationships through this dispute process. However, a meeting of the Director and EPA staff with representatives of the Respondents to discuss their unspecified issues and requests should occur outside of the dispute process. In fact, EPA staff believes a meeting to discuss how we can work more productively and efficiently in the future would be a good idea. With that said, the Director should clarify for the Respondents that any discussion will not include relinquishing any enforcement authority.

B. No amendment to the AOC or the review, comment, and approval process is appropriate or necessary.

If the Director determines that meeting on protocols can be a matter addressed through the dispute process, EPA's actions related to the second draft BHHRA were in compliance with its reserved rights and authorities under the AOC, CERCLA, and NCP, and there is no reason to consider amendments to the AOC as detailed in Section II. of this Response. The Respondents did not provide a specific proposal regarding the "documented protocols" it desires. However, they have made clear they do not like that EPA modified their second draft BHHRA without conferring with them about the reasons for modifying the document or the specific modifications we were making. As detailed above, EPA was under no requirement to notify the Respondents

prior to modifying the BHHRA, nor was EPA required to discuss the basis for our modifications prior to providing them the modified BHHRA. Nonetheless, EPA in fact did notify Respondents as far back as July 2011 that we were modifying the document and we told them generally the problems we saw that was leading to us do the modifications. See Tabs 18 and 19.

The EPA has had numerous and extensive interactions with the Respondents as part of the process of review and approval of a multitude of major and minor project deliverables over the past 10 years. The typical process of reviewing deliverables, providing comments, clarifying comments, directing changes and resolving disagreements over comments and directed changes included frequent meetings between EPA and the Respondents technical staff and project managers and required significant investment of time and staff resources. The issues were often technically complex and both parties attempted to work collaboratively to fully understand and resolve areas of disagreement.

Numerous sampling plans, technical evaluations, summary reports, work plans, and other precursors to the RI and risk assessment reports were completed and approved in this manner. For major deliverables, the process often involved use of comment resolution tables to methodically clarify, track, and narrow the list of disagreements. In many cases, agreements were reached through the comment resolution process, the Respondents modified the documents in accordance with EPA's comments and direction, and documents were subsequently approved. For other deliverables, EPA needed to "cut off" unproductive meetings and conversations after a period of time when it became apparent that agreements on certain issues could not be reached and direct the Respondents to make the necessary changes. The EPA typically was more directive in requiring changes after allowing the Respondents the opportunity, or in some cases multiple opportunities, to modify unacceptable documents to correct deficiencies. Up to this point, the Respondents have not disputed EPA's direction, although the Respondents too have made it clear on the record several times that, although they would perform required work, they still disagreed with EPA's direction.

The reality is that EPA has not taken a heavy hand throughout the RI/FS process, and has sought to work cooperatively to the extent possible. In doing so, the Remedial Project Managers (RPMs) at times through the process may have agreed to a path forward demanded by the Respondents to keep the RI/FS and risk assessment moving forward. However, at the time the full ramifications and consequences of those agreements became apparent in the second draft BHHRA, a correction in course was needed and EPA modified the text of the BHHRA to make those corrections. Such is the right and in fact duty of the EPA as the delegated authority to make remedy decisions under CERCLA. Another reality the Respondents must face is that changes in course and perceived agreements with the EPA RPMs may very well happen until the Record of Decision is issued. As the RI/FS and preferred alternative are reviewed by Regional management, the Office of Regional Counsel, and EPA Headquarters, changes may occur at any time through that review process. Also, statutory mandated public participation too may result in changes to the proposed remedy or underlying technical work performed by the Respondents.

Although the agency should agree to meet with the Respondents to discuss their proposals, there will be certain constraints on the nature and scope of amendments to the review and approval process. Just from the tenor and statements made in their Opening Statement, the nature of the amendments the Respondents are seeking appear problematic under the CERCLA statutory scheme. This is because, while the AOC is on consent, CERCLA is not a voluntary cleanup program. To assure legal documents comply with the law and regulations and provide consistency in process and enforcement, the EPA depends on nationally issued model documents, most relevant here, model administrative consent orders. Although the Respondents have not said what protocols they seek, it is likely amendments to the AOC review and approval procedures will need to be thoroughly vetted through the Office of Regional Counsel in consultation with the Office of Site Remediation Enforcement in EPA Headquarters.

VI. CONCLUSION

The RI/FS has been in process for 12 years in large part due to the complexity of the site, but also because additional time and resources that have been required in seeking agreement with the Respondents. Seeking consensus is a time consuming process, especially when so many parties are involved in the process. The record is clear that EPA has sought to cooperatively work through technical issues along the way with the Respondents. The AOC, as well as the statute, provides EPA with the ultimate approval and decision-making authority. The Respondents, in signing the AOC, get to participate in the process and when they disagree with comments and directions by EPA, the AOC provides them with a dispute resolution process which elevates the issue for final decision to a high management level within the Office of Environmental Cleanup.

Now that the risk assessments, RI Report and FS Reports are moving to completion, it is imperative these fundamental documents that will inform and support the cleanup decisions for the Portland Harbor Superfund Site be acceptable to EPA, comply with CERCLA, the NCP, and EPA guidance, and are documents that the EPA can defend in selecting a remedy for this site.

Rather than view the process as broken, the process actually worked as the AOC was designed. EPA modified the BHRRA in a way it could approve it more quickly. Even though Respondents chose to dispute the modifications, the informal dispute process led to reaching many agreements on the BHHRA and narrowing down those issues the Respondents sought to take to the Director. There are major documents under review right now, the Baseline Ecological Risk Assessment, the second draft RI report, and the first draft FS. How the EPA responds to those documents will be in compliance with our authority under the AOC and CERCLA with the overall goal of achieving acceptable documents in as timely a manner as possible.

Based on our responses and the administrative record created for this dispute, EPA respectively requests the Director to make the following decisions:

1. Uphold EPA's determination under the AOC that Respondents failed to produce a deliverable of acceptable quality, or otherwise failed to perform in accordance with the

requirements of the AOC because they did not adequately address all of EPA's comments;

2. Adopt EPA's positions, as presented in this response, on the appropriate Reasonable Maximum Exposure and Central Tendency Exposure Scenarios for recreational and subsistence fishers for incorporation, as appropriate, into the text and tables and figures of the final BHHRA;
3. Agree with EPA's positions on exposure scenario and uncertainty language regarding domestic water and clam consumption (which would require no additional changes to the draft BHHRA text);
4. Agree with EPA's positions regarding the Executive Summary, Table of Contents, and Conclusion sections;
5. Adopt the revised BHHRA, dated September 17, 2012, [Respondents' Exhibit 1 and EPA's Exhibit 13] which incorporates a majority of the resolutions reached between Respondents and EPA as of September 14, 2012, and require that the resolutions of the disputed technical issues (2, 3, and 4, above) from this dispute will be incorporated, if necessary, by EPA into the final document[18]; and
6. Determine that the Respondents' request to establish protocols for better working relationships would be an amendment to the review and approval process and enforcement provisions of the AOC and, thus, is not relief that can be addressed through the dispute resolution process.

[18] EPA agrees that substantial progress was made during the informal dispute process and that Tables 1 and 2 generally reflect the specific issues raised by Respondents that they and EPA reached some form of resolution on. But it is only the specific agreed-upon language reflected in the red-lined text of the Sept 17, 2012 BHHRA that has been agreed to so far. Thus, EPA does not believe it is necessary or appropriate for the Director to approve Tables 1 and 2 themselves.

From: Deb Yamamoto
To: Bob Wyatt
Cc: Kristine Koch; Elizabeth Allen; Cami Grandinetti; Lori Cora; Sheila Fleming; jim.mckenna@verdantllc.com; Jennifer Woronets; Steve Parkinson
Subject: Re: Confirmation of Extension for Informal Dispute Resolution
Date: Wednesday, August 01, 2012 5:13:33 PM

Bob,

EPA confirms that we agree to an extension of the informal dispute resolution period until September 7, 2012, based on the LWG's commitment to provide EPA the LWG's comments on unacceptable, substantive changes made in EPA's modified Baseline Human Health Risk Assessment no later than August 15, 2012. As stated in the meeting, EPA wants the issues limited to those with technical or factual substance. We agree that the 30-day extension is without prejudice to any claims or defenses in this dispute by either party. We also confirm that EPA considers written or oral communications during this informal dispute resolution process to be settlement negotiations and confidential to the extent allowed by law.

Deb Yamamoto, Manager
Site Cleanup Unit 2
Environmental Cleanup Office
U.S. Environmental Protection Agency
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(206) 553-7216

"Wyatt, Robert" ---08/01/2012 03:30:00 PM---Deb: Per our informal dispute resolution settlement meeting yesterday, we have confirmed with the LW

From: "Wyatt, Robert" <rjw@nwnatural.com>
To: Deb Yamamoto/R10/USEPA/US@EPA
Cc: Chip Humphrey/R10/USEPA/US@EPA, Elizabeth Allen/R10/USEPA/US@EPA, "jim.mckenna@verdantllc.com" <jim.mckenna@verdantllc.com>, Jennifer Woronets <jworonets@anchorqea.com>, Kristine Koch/R10/USEPA/US@EPA, Sheila Fleming/R10/USEPA/US@EPA, Lori Cora/R10/USEPA/US@EPA, Steve Parkinson <sparkinson@jzplaw.com>
Date: 08/01/2012 03:30 PM
Subject: Confirmation of Extension for Informal Dispute Resolution

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Deb:

Per our informal dispute resolution settlement meeting yesterday, we have confirmed with the LWG technical team that we can provide EPA with our comments on unacceptable substantive changes made to the Baseline Human Health Risk Assessment by Wednesday, August 15th. With the 30 day extension of the informal dispute resolution period to September 7, 2012 that we discussed. This allows three weeks for the parties to work through these issues and see if an agreement is possible. We trust that this is sufficient time and that the 30 day extension of the informal dispute resolution period is hereby approved. Please confirm by reply email.

We also want to confirm our agreement that the 30 day extension is without prejudice to any claims or defenses in this dispute by either party.

Lastly, we want to confirm our agreement yesterday that written communications between EPA and the LWG during the informal negotiation period will be maintained as settlement confidential consistent with FRE 408, as will oral communications concerning the substance of our settlement negotiations. As we

are sure EPA is aware, there has been substantial media coverage of EPA's determination that the BHHRA was deficient and that the LWG is in violation of the Consent Order, and the LWG and its members will continue to respond to such coverage as we deem appropriate.

Thank you,

Bob

EXHIBIT 3

From:	Lori Cora
To:	Steve Parkinson
Cc:	Bob Wyatt; Kristine Koch; Chip Humphrey; Deb Yamamoto; Elizabeth Allen; "jim.mckenna@verdantllc.com"@epamail.epa.gov; Jennifer Woronets
Subject:	Portland Harbor BHHRA Dispute
Date:	Friday, July 27, 2012 2:43:19 PM
Attachments:	2012-07-27 Basis for Noncompliance.docx Draft Agenda - Portland Harbor Dispute Resolution Meeting 7-31-2011.docx

Hello, Steve. On behalf of the Office of Environmental Cleanup, I am forwarding EPA's draft list of comments on the 2nd Draft BHHRA that we contend were not fully addressed and, thus, provide the basis for our determination under the AOC that the LWG was out of compliance. EPA reserves the right to identify additional comments and directions that were not fully addressed during the dispute process. As we discussed in our meeting on July 16, 2012, the four major deficiencies listed in EPA's June 22 letter were some, but not all, of the reasons EPA modified the BHHRA. The attached list provides the basis for the noncompliance determination. We will be happy to discuss the LWG's views on this list but believe our time on Tuesday would be best spent discussing the LWG's issues with EPA's modifications.

I am also attaching the draft agenda for Tuesday's meeting. We welcome comments or additions. As Deb Yamamoto requested of Bob Wyatt earlier, EPA's risk assessor will be in attendance and we believe the LWG's human health risk assessor(s) should attend to help discuss and explain the specific issues being disputed.

We look forward to hearing from the LWG on the agenda and seeing you all on Tuesday.

(See attached file: 2012-07-27 Basis for Noncompliance.docx)(See attached file: Draft Agenda - Portland Harbor Dispute Resolution Meeting 7-31-2011.docx)

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July 27, 2012

Basis for EPA's Determination the May 2, 2011 Draft BHHRA was Not In Compliance with AOC:

1. **PBDE Evaluation was not adequately addressed in BHHRA.**

EPA July 16, 2010 comment #117:

> *Delete the last sentence of the second paragraph. The first full paragraph on page 111 discusses the results of PBDE analysis for sturgeon, salmon and lamprey done as a part of the ODHS study, and then performs a conservative risk calculation using maximum detected values for PBDEs. Although this is useful information for salmon, sturgeon and lamprey, it is not directly applicable to resident fish species (e.g., carp and bass) that tend to have higher levels of bioaccumulative compounds (like DDX, PCBs and dioxins/furans) than salmon, lamprey and sturgeon. Without resident fish data on PBDEs, the conclusion that PBDEs are unlikely to contribute to the overall risks is not defensible. The EPA Region 10 lab has recently completed analyses of PBDEs in selected samples of resident biota from the PH Round 3 sampling (20 carp samples (10 fillet and 10 rest of body), 38 bass samples (19 fillets and 19 rest of body), and 6 clam samples). This data was recently made available to the LWG.*

EPA December 8, 2010 Data Lockdown comment #2 (directed):

> *The data lockdown date for the risk assessments will remain unchanged (i.e., June 2008) with the following exceptions: A) The recent PBDE fish tissue data shall be presented in the RI and used to evaluate risks to human health in accordance with all fish consumption exposure scenarios. The recently issued reference dose values available on EPA's Integrated Risk Information System (IRIS) data bases should be used for the risk estimates. The risk assessment information for PBDE's may be presented as an addendum...*

EPA December 8, 2010 BHHRA comment (directed):

> *<u>BHHRA Comment – Inclusion of the PBDE Fish Tissue Data in the BHHRA:</u>*
> *This comment was provided to the LWG as part of our data lockdown comment with respect to the RI Report (see above). EPA disagrees that the PBDE analysis was solely for the purpose of method development. EPA has determined that the PBDE data is sufficient to assess risk within Portland Harbor, support regional watershed efforts and monitor the effectiveness of the site remedy with respect to PBDEs. As a result, EPA direct the LWG to present the risks associated with PBDEs in bass, carp and clam tissue consistent with the fish consumption scenarios developed in the Portland Harbor baseline human health risk assessment. This comment shall not change the agreed upon PRGs to be used in*

the draft FS. EPA reserves the right to require the development of PRGs for PBDEs in the future (e.g., proposed plan and/or final FS) if deemed necessary.

EPA February 25, 2011

The LWG has been aware for several years that the inclusion of PBDEs in the revised draft BHHRA would be required. Inclusion of this information in the revised draft BHHRA does not warrant the requested schedule extension. Including PBDEs in the BHHRA was identified by EPA in December 2005 as a data gap. During development of Round 3B field sampling plans, EPA and the LWG agreed that EPA's Manchester Laboratory would perform the chemical analysis. The draft BHHRA presented an estimated maximum potential HQ of less than 1 for PBDEs using the maximum detected concentration for total PBDEs in the ODHS dataset (salmon, sturgeon and lamprey tissue) and the lowest RfD for any PBDE congener. EPA subsequently provided the results of the additional tissue analysis for carp and bass to the LWG on November 12, 2009. With the additional data analysis, EPA estimated that consuming fish contaminated with PBDEs resulted in hazard quotients ranging from 1 to 2. The LWG did not agree to include the PBDE data and evaluation in the BHHRA so on December 8, 2010, EPA directed the LWG to evaluate risks associated with PBDEs. EPA did not require the development of PRGs for PBDEs since tissue-sediment relationships have not been developed for PBDEs.

EPA April 11, 2011 comment #4:

It appears that risk and hazard estimates from exposures to polybrominated diphenyl ethers (PBDEs) are to be presented entirely in an attachment to the revised BHHRA. EPA requested that PBDE risk and hazard estimates be included to provide a full characterization of the risks associated with contamination at the Portland Harbor site. Hence, estimated risks and hazard from PBDEs ultimately need to be incorporated into the tables presenting cumulative risks and hazard for the different exposure scenarios.

EPA April 27, 2011 email:

Elizabeth Allen and Laura Kennedy recently discussed possible ways to meet the intent of Comment 4 of EPA's April 11, 2011 comments on LWG's March 17, 2011 submittal of the revised risk calculations for the PH BHHRA. Their recommendation is that a discussion of the contribution of carcinogenic risks and noncarcinogenic hazard due to PBDE exposures be presented in the risk characterization section of the BHHRA. As appropriate, PBDEs will be identified in Table 5-189 for further evaluation. EPA concurs with the recommended approach. The intent of EPA's comment 4 was not to require inclusion of PBDE

risks in each receptor-specific and location-specific table in the BHHRA, and presentation of that information in an attachment is also acceptable.

LWG May 6, 2011 Response:

As clarified in EPA's email on April 27, 2011, PBDEs do not need to be incorporated in the tables presenting cumulative risks and hazards. Consistent with EPA's email, the Risk Characterization section in the Final BHHRA will include a discussion of the contribution of carcinogenic risk and noncarcinogenic hazard due to PBDE exposures. PBDEs are identified in the tables of contaminants posing cancer risks greater than 1 x 10-6 or hazard quotients greater than 1 in the Draft Final BHHRA.

EPA Rational for Deficiency:

PBDEs were not included in Table 5 calculations of cumulative risk and hazard, nor were they discussed in the risk assessment document in this regard. The draft BHHRA only discusses PBDEs as being assessed separately in Attachment F3.

2. **RME and CTE identifiers were not incorporated into BHHRA tables. EPA July 16, 2010 comment #52 and #20 was not adequately incorporated .**

EPA July 16, 2010 comment #52 (Section 3.4, page 31):

In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean" EPC relative to one based on a 95 percent UCL or maximum concentration if misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. Consistent with EPA guidance (1992, 2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates.

EPA July 16, 2010 Comment #20 (ES.5, page 7):

Throughout the text, figures, tables and maps, the phrase "RME Exposure..." should be used in place of "95% Upper confidence limit (UCL) or Maximum.

LWG Resolution from 11-18-2010 Table (comment #52 and #20):

> *The EPCs will be described in a factual manner in the BHHRA (i.e., the EPC will be identified as the mean, 95% UCL, or maximum). The terms RME and CT will not be used in reference to the EPCs.*

EPA April 11, 2011 Comment #1:

> *Per EPA Specific Comment 52 on the draft Portland Harbor BHHRA, the tables should be revised to note whether a Central Tendency Exposure (CTE) or a Reasonable Maximum Exposure (RME) exposure scenario is presented. Accordingly, in all instances "95% UCL/Maximum Exposure Scenario" should be changed to "RME" in the title. EPA agreed that actual exposure point concentrations could be referred to specifically on the basis of the value they represented (arithmetic mean, 95 percent upper confidence limit on the arithmetic mean, or the maximum detected concentration),* ***but that the exposure scenarios would be referred to as either CTE or RME as consistent with EPA risk assessment guidance and policy (emphasis added).***

LWG May 2, 2011 Response:

> *Text was added to define the use of EPCs (i.e., the EPC is identified as the mean, 95% UCL, or maximum). The terms RME and CT were not used in reference to the EPCs. Risks were evaluated using both the 95% UCL/maximum and mean EPCs.*

LWG May 6, 2011 Response:

> *For sediment and water exposure scenarios, the tables in the Draft Final Baseline Human Health Risk Assessment (BHHRA) have been revised to note whether a central tendency or reasonable maximum exposure scenario is presented. As discussed during the October 15, 2010 meeting, the fish and shellfish ingestion scenarios involve a range of ingestion rates, so the tables do not present a RME or CTE scenario. For those scenarios, the table titles in the Draft Final BHHRA have been revised to reference the exposure point concentrations and do not refer to the 95% UCL/maximum or mean as exposure scenarios.*

EPA Rational for Deficiency:

The LWG did not clearly and factually define which EPCs were used to evaluate the RME and CT in this risk assessment in the tables. Thus, Section 3 Tables were not changed to reflect this comment nor were Section 5 Tables for fish consumption.

3. **EPA July 16, 2011 directed comment #148 was not adequately incorporated.**

EPA July 16, 2011 comment #148 (Section 7.2.5.3, page 123):

> *Revise the following sentence in the first paragraph as shown:*
>
> *Although fishers normally fish and/or collect those resources that are available in their area, it is not known to what extent fishers would substitute alternative local types of shellfish. ~~if the shellfish in the survey were not available.~~*

LWG Resolution from 9-15-2010 Table:

> *The LWG disagrees with EPA's directed changes requiring the removal of factual information from the draft BHHRA. The LWG believes that the addition of statements asserting a need for remediation or goals of remediation in the BHHRA is not consistent with guidance. As discussed at the August 20th and September 9th meetings, factual (i.e., objective) language can remain in the revised BHHRA. Judgmental language (both that in the draft BHHRA and that directed by EPA) will not be included in the revised BHHRA. The need for remediation or goals of remediation will not be discussed in the revised BHHRA. Discussion of remediation goals will be included in the FS consistent with the RAOs.*

LWG May 2, 2011 Response:

> *The sentence was revised to delete the text per the comment. The inserted text was not included.*

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.2.5.3, page 128):

> *It is not known to what extent fishers substitute alternative local types of shellfish.*

EPA Rational for Deficiency:

This was a directed comment that specified that the text be modified to read *"Although fishers normally fish and/or collect those resources that are available in their area, it is not known to what extent fishers would substitute alternative local types of shellfish."* The first part of the sentence was not included as per the direction.

4. **EPA July 16, 2011 comment #17 was not adequately incorporated.**

EPA July 16, 2011 Comment #17 (ES.3, page 5):

> *Delete the last sentence in the last paragraph in ES.3:*
>
> *"~~Because many of the exposure scenarios that were evaluated in the BHHRA are highly variable and do not have standard default exposure factors, uncertainties associated with the exposure factors are anticipated to have significant impacts on the risk estimates.~~"*
>
> *The phrase "highly variable" represents a subjective judgment, and will have different meanings to different readers of the assessment. The analysis of uncertainties should avoid unsupported claims about the relative variability of different exposure scenarios. An objective discussion of uncertainties for each scenario and their relationship to the quantitative risk estimates is adequate.*

LWG Resolution from 11-18-2010 Table:

> *This issue was addressed in the responses to EPA's Directive Comments. [regarding deletion of factual statements and comments on remedy]*
>
> *September 15, 2010 response.*
>
> *The LWG disagrees with EPA's directed changes requiring the removal of factual information from the draft BHHRA. The LWG believes that the addition of statements asserting a need for remediation or goals of remediation in the BHHRA is not consistent with guidance. As discussed at the August 20th and September 9th meetings, factual (i.e., objective) language can remain in the revised BHHRA. Judgmental language (both that in the draft BHHRA and that directed by EPA) will not be included in the revised BHHRA. The need for remediation or goals of remediation will not be discussed in the revised BHHRA. Discussion of remediation goals will be included in the FS consistent with the RAOs.*

LWG May 2, 2011 Response:

> *The sentence was revised to use the term "modifying factors" and provide specific examples of considerations in deriving those factors.*

LWG May 2, 2011 Revised Draft BHHRA language (Section ES.4, page 5):

> *Modifying factors, which typically range from two to three orders of magnitude (100 to 1,000 times), are often used by EPA in deriving toxicity values for human health given the level of confidence in the toxicological data, the intra-species differences (i.e., animal to human), and the inter-species differences to account for sensitive human subpopulations.*

EPA Rational for Deficiency:

The revised text fails to clarify that modifying factors aren't used in the derivation of slope factors. Since these represent probabilities, the uncertainty is expressed by using a UCL on the slope of the line.

The original risk assessment text used the term "uncertainty or variability factors, and referred to a typical range of 100 to 1,000. Those specific numbers cited appear to represent the "uncertainty factors" used in the derivation of noncancer toxicity criteria (reference doses or reference concentrations), which tend to be factors of 10, for things like accounting for interspecies differences in metabolism, or that there may be particularly sensitive individuals in a heterogeneous human population and we may have tested a group of genetically homogenous animals. Sometimes the uncertainty factors were also combined with modifying factors, intended to reflect scientific uncertainties of the study and database not explicitly treated with standard uncertainty factors. So "uncertainty factor" and "modifying factor" are specific, discrete terms with different definitions and neither is used in the derivation of cancer slope factors, which are really the output of various statistical regression models. As such, there is no uncertainty factors used for cancer risk assessments, as the values are already expressed as some confidence interval. The comment was in part an attempt to point out this distinction, the LWG response was to go from uncertainty factors to modifying factors, which is technically incorrect. In addition, although the comment did not provide specific, word-for-word direction, the LWG was willing to change the definition of uncertainty factors, but failed to address the part of the comment that said they should also note that it is possible that hazard may be underestimated if certain endpoints were not the focus of the toxicological studies. However, the LWG has steadfastly refused to discuss uncertainties when they may indicate the risk could possibly be underestimated.

5. **EPA July 16, 2010 comment #28 was not adequately incorporated.**

EPA July 16, 2010 Comment #28 (Section 1.0 Introduction, page 12):

> *The document suggests that this report is somehow different from other risk assessments because EPA directed the use of conservative assumptions. In fact, risk assessments performed under guidance from other federal agencies, states, and even other countries, assess risks and inform risk management decisions*

based on assumptions that report risks in the upper range of those possible. The risk assessment for PH is thus typical in this regard. Accordingly, with the exception of the first sentence, the text in the third paragraph should be deleted.

Resolution from 11-18-2010 Table:

This issue was addressed in the responses to EPA's Directive Comments. [regarding deletion of factual statements and comments on remedy]

September 15, 2010 response.

The LWG disagrees with EPA's directed changes requiring the removal of factual information from the draft BHHRA. The LWG believes that the addition of statements asserting a need for remediation or goals of remediation in the BHHRA is not consistent with guidance. As discussed at the August 20th and September 9th meetings, factual (i.e., objective) language can remain in the revised BHHRA. Judgmental language (both that in the draft BHHRA and that directed by EPA) will not be included in the revised BHHRA. The need for remediation or goals of remediation will not be discussed in the revised BHHRA. Discussion of remediation goals will be included in the FS consistent with the RAOs.

LWG May 2, 2011 Response:

The paragraph was modified to indicate that the risk assessment is consistent with guidance and identifies assumptions that may impact the risk estimates in a factual manner.

LWG May 2, 2011 Revised Draft BHHRA language (Section 1.0, page 18):

The LWG has worked with the United States Environmental Protection Agency (EPA) to develop the methods and assumptions used in this BHHRA. At the direction of EPA, this BHHRA incorporates assumptions to provide a health protective assessment of risks associated with contaminants present at the Site, which is consistent with EPA guidance on risk assessment (1989). For many of the exposure scenarios evaluated in this BHHRA, upper-bound literature values are used to quantify exposure due to the lack of site-specific exposure information. In some cases, the maximum detected concentrations are used to quantify long-term exposures, which may not be representative of ongoing exposures in the Study Area. Therefore, the results of the BHHRA have a margin of conservatism built into the risk conclusions consistent with EPA guidance (1989).

EPA Rational for Deficiency:

The statement is still not accurate. The assessment of human health risks is to be made on a reasonable maximum exposure, which is defined in EPA guidance (RAGS Part A, EPA 1989) as the highest exposure that is reasonably expected to occur at a site. For this reason, the intake variable values for Superfund exposure assessments are selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. The selection of these values has nothing to do with the lack of site-specific values.

6. **EPA July 16, 2010 comment #38 was not adequately incorporated.**

EPA July 16, 2010 comment #38 (Section 2.4, Table 2-13):

> *It is not clear why only one of the surface water samples (W020) from Swan Island Lagoon was used for COPC screening for transients and recreational beach exposures and for the domestic water source. Please add an explanation, or use all the data in the COPC screen.*

LWG Resolution from 11-18-2010 Table:

> *EPA will not require the changes to the data sets used in the BHHRA that were requested in the identified non-directive comments.*

LWG May 2, 2011 Response:

> *Per agreement at the October 15, 2010 meeting, the dataset used for screening COPCs for transients and beach exposures was not changed.*

EPA Rational for Deficiency:

Since the agreement was that the data set would not change, an explanation in the BHHRA Section 2.4.2 was to be provided per the comment. However, Section 2.4.2 does not provide any explanation for why only one of the surface water samples (W020) from Swan Island Lagoon was used for COPC screening for transients and recreational beach exposures and for the domestic water source as requested in the comment.

7. **EPA July 16, 2010 comment #50 was not adequately incorporated .**

EPA July 16, 2010 comment #50 (Section 3.3.5.2, page 39):

> *In the second sentence, change the word "suggest" to "show" in the following sentence:*
>
> *"The results of the survey show ~~suggest~~ that tribal members have higher fish ingestion rates than the general public."*

LWG Resolution from 11-18-2010 Table:

> *LWG Response: EPA provided suggested revisions to the text of the BHHRA. The LWG proposes modifications to the suggested language for purposes of clarity and/or consistency. EPA agrees with the response.* [Note: 11-8-2010 Table does not supply specific language.]

LWG May 2, 2011 Response:

> *The sentence was revised with the following modifications:*
>
> *"The results of the survey show that tribal members surveyed generally have higher fish ingestion rates than the general public."*

EPA Rational for Deficiency:

The proposed language inappropriately qualifies the survey results inconsistent with EPA's provided language.

8. **EPA July 16, 2010 comment #76c was not adequately incorporated.**

EPA July 16, 2010 comment #76 (Section 5.2.1, pages 71-76):

> *A summary discussion should be presented at the end of this section that references a summary table showing all of the beaches that are above risk levels of 10^{-6}, 10^{-5}, and 10^{-4} for each receptor, with contaminants included. This presentation should also include graphs for tribal adult exposure to beach sediments, for total cancer risk by beach, and for cancer risk for arsenic, dioxin/furan TEQ, B(a)P, and total cPAH by beach. Other beach scenarios (e.g., recreational users, transients, and dockside workers) should also be shown. The graph should be organized by river mile (east and west) with corresponding sample numbers for each river mile shown.*
>
> *a) The total HI calculated by summing the HQs for individual chemicals should be added to all of the risk characterization tables. Tables showing endpoint-specific His can be eliminated for those scenarios where the total His for all*

chemicals are less than 1.0, but should be shown for endpoints with His that exceed 1, if more than one endpoint shows such a result.

b) *Maps 5-1, 5-2, and 5-3 should include the calculated risk values for those beaches where estimated risks are greater than 1 x 10^{-6}.*

c) *The discussions of arsenic are vague throughout this section and elsewhere in the risk characterization section. The discussions provided do not allow the reader to evaluate arsenic contribution to risks or at which beaches arsenic concentrations are greater than background levels. The points that need to be made are 1)arsenic occurs both naturally and as a result of environmental releases, and 2) assuming an estimated background of 7 mg/kg, the degree to which background concentration contribute to the EPC and risk should be described.*

Resolution from 11-18-2010 Table:

LWG Response: EPA requested that a summary discussion be included at the end of the risk characterization section for each exposure medium evaluated in the BHHRA. The LWG proposes that the summary discussion should identify those chemicals with cancer risks greater than 10^{-6}, 10^{-5}, and 10^{-4} and hazard quotients greater than 1.] EPA agrees with the response.

LWG May 2, 2011 Response:

A summary discussion was added. Chemicals resulting in risks greater than 1 x 10^{-6} were included in the summary. Risks greater than 1x10^{-6} were presented in revised maps.

EPA Rational for Deficiency:

Neither the LWG's response nor the revised BHHRA address part c of EPA's comment. Further, the LWG simply subtracted out background from the EPC values and presented this in maps, which is different than discussing the degree to which background concentrations contribute to the EPC and risk (per the comment) and inconsistent with EPA's Risk Characterization Handbook and The Role of Background in the CERCLA Cleanup Program guidance. We made a comment and their response went the wrong direction.

9. **EPA July 16, 2010 comment #99 was not adequately incorporated.**

EPA July 16, 2010 comment #99 (Section 5.2.6, page 91-92):

The document concludes that Study Area-wide cancer risks from consumption of undepurated clams are 2 to 3 times higher than those from Study Area-wide cancer risks from depurated clams, and that corresponding non-cancer hazards are 1 to 2 times higher. The database for COPCs in depurated clam tissue is

limited to 5 of the 22 clam samples, and these 5 samples are from the northern stretch of the river (1E and 2W) and the southern stretch of the river (10W,11E, and 12E). ***It is not appropriate to compare risks from these 5 depurated samples from the edges of the site to the 22 non-depurated clam samples from the entire length of the site from RM 1 to RM 12, or to compare non-depurated clams to depurated clams from only the edges of the site (1E and 2W; 10W, 11E, and 12E) and assume that the results are representative of the entire site [emphasis added].*** *As no supporting calculations are presented in the draft BHHRA, it is not clear what samples were used for these calculations, and EPA cannot determine if the calculations are correct. These supporting calculations should be included in Attachment F5. In drawing conclusions from this analysis, the discussion should be clear that these data only provide information in 5 sampling locations, all of which are on the edges of the site rather than in areas with particularly high cPAH concentrations.*

LWG Resolution from 11-18-2010 Table:

[LWG Response: The BHHRA will be revised consistent with the comment.] EPA agrees with the response.

LWG May 2, 2011 Response:

Revised per comment.

EPA Rational for Deficiency:

While the revised text (p. 102) notes that the depurated samples were collected at the edges of the study area, there is still is an inappropriate comparison of risk between the depurated and undepurated clams collected at the Site. The distribution of risk relative to the distribution of sediment contaminant concentrations and the appropriate comparison of depurated and undepurated clams gathered from the same location show that there is very little difference in the risk and hazard. Consequently, it is not consistent with our comment to compare depurated samples on a site-wide basis since they are not representative of site-wide risk and hazard.

10. **EPA July 16, 2010 comment #106 was not adequately incorporated.**

EPA July 16, 2010 comment #106 (Section 7.0, page 104):

Revise the first paragraph to delete the following sentence:

"In a deterministic risk assessment multiple conservative assumptions compound to result in an estimate of risk that can be many times (or orders of magnitude) greater than the likely actual risk posed by a particular site."

There is no information presented in this section or anywhere else in the risk assessment to support such a claim.

LWG Resolution from 11-18-2010 Table:

This issue was addressed in the responses to EPA's Directive Comments. [regarding deletion of factual statements and comments on remedy]

September 15, 2010 response.

The LWG believes that the combination of multiple conservative assumptions does result in risks for certain scenarios that are greater than those that are "reasonably anticipated to occur at the site", which is the definition of reasonable maximum (RAGS A, Page 6-4). For example, it is not anticipated that an individual would eat 19 meals of whole body carp caught within the Study Area that had no preparation or cooking every single month for 30 years. However, the LWG recognizes that the concept of reasonable maximum exposure (RME) involves the use of professional judgment. Per RAGS Volume 3 Part A, "the 90th to 99.9th percentiles of the risk distribution are collectively referred to as the ***recommended RME range****", and the risk manager chooses the specific percentile to represent the RME individual.*

As discussed at the September 9th meeting, ***language regarding the compounding of conservative assumptions will not be included in the revised BHHRA. [emphasis added].*** *Factual information about the range of the exposure assumptions and how the combination of those assumptions may fall within the RME range of 90th to 99.9th percentiles can be included in the revised BHHRA.*

LWG May 2, 2011 Response:

The sentence was revised to reflect that assumptions can compound to result in a risk estimate at the upper end of the risk range.

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.0, page 109):

In a deterministic risk assessment, conservative assumptions can compound to result in an estimate of risk that is at the upper end of the probable risk range.

EPA Rational for Deficiency:

The LWG's draft BHHRA did not address EPA's comment nor was it consistent with the agreement documented. EPA's comment clearly indicated that the LWG had not supplied any information in support of their compounding statement and the draft BHHRA also did not. Therefore, the statement too is a judgment or opinion which the LWG agreed to eliminate from the BHHRA.

11. **EPA July 16, 2010 comment #111 was not adequately incorporated.**

EPA July 16, 2010 comment #111 (Section 7.1.3, page 103):

> *The following statement occurs in the first paragraph: "Depending on the species and chemical, the difference in concentrations between fillet and whole body tissue can be minimal or more than a factor of 10, as discussed in Attachment F5." As discussed in our comments on Attachment F5, a table should be provided that shows data used and results that supports the conclusion (e.g., "factor of 10") presented here. Analyses not reported in the risk assessment cannot be evaluated or approved by EPA.*

LWG Resolution from 11-18-2010 Table:

> *[LWG Response: The BHHRA will be revised consistent with the comment.] EPA agrees with the response.*

LWG May 2, 2011 Response:

> *The data and results supporting the conclusion are presented in Attachment F6 (formerly Attachment F5).*

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.1.3, page 111):

> *Depending on the species and chemical, the difference in concentrations between fillet and whole body tissue can be minimal or more than a factor of 10, as discussed in Attachment F6.*

EPA Rational for Deficiency:

No information is presented in Attachment F6 to support the statement made here which was what EPA agreed had to be included for the statement to stay. The sentence needs to be deleted as directed.

12. **EPA July 16, 2010 comment #112 was not adequately incorporated .**

EPA July 16, 2010 comment #112 (Section 7.1.4, page 107-108):

> *This section concludes that, "With the exception of a few metals, average chemical concentrations were higher in undepurated clam tissue collected at the Study Area than in depurated clam tissue." The database for COPCs in depurated clam tissue is limited to 5 of the 22 clam samples, and these five samples are from the northern stretch of the river (1E and 2W) and the southern stretch of the river (10W, 11E, and 12E). Hence it is not evident that the results from these samples are representative of conditions from the entire length of the site from RM 1 to*

RM 12. At a minimum, the risk assessment should discuss the uncertainty associated with such a limited data set for depurated clam tissue, and present a balanced discussion of the appropriateness of extrapolating these limited results to represent tissue concentrations in more contaminated areas of the site.

LWG Resolution from 11-18-2010 Table:

[LWG Response: The BHHRA will be revised consistent with the comment.] EPA agrees with the response.

LWG May 2, 2011 Response:

Uncertainties in the comparison of depurated and undepurated samples are discussed.

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.1.4, page 112):

6.1.4 Use of Undepurated Tissue to Represent Clam Consumption

Clam tissue throughout most of the Study Area was analyzed as undepurated samples, and a limited number of clam samples were depurated before analysis. A common practice in the preparation of clam tissue for consumption includes depuration, although undepurated clam may also be consumed. The amount of COPC-containing particles within the gut of bivalves can vary widely; however, studies have demonstrated that the sediment content in the gut of bivalves could represent up to 39% of the total body load of metals (Wallner-Kersanach et al. 1994). With the exception of a few metals, average chemical concentrations were higher in undepurated clam tissue collected at the Study Area than in depurated clam tissue collected at the Study Area. However, depurated clam tissue accounted for only five of the 22 clam samples collected for the BHHRA dataset, and the depurated samples were collected from edges of the site (northern and southern stretches). Therefore, there are uncertainties associated with comparing depurated and undepurated tissue in the BHHRA dataset. These concentrations are shown in the EPC tables in Section 3 (Tables 3-24 and 3-25). Using analytical concentrations of undepurated tissue to represent tissue consumption throughout most of the Study Area provides a healthprotective approach to assessing risk from clam tissue consumption.

EPA Rational for Deficiency:

The Table F6-13 is very difficult to read, but seems to show no discernable pattern. The LWG did not statistically prove their point therefore they did not address the comment and the statement should have been deleted as directed.

13. **EPA July 16, 2010 comment #155 was not adequately incorporated.**

EPA July 16, 2010 comment #155 (Section 7.2.3.4, page 123):

> *According to the information presented in Attachment F5, the ratios between the maximum and minimum concentration values shown are less than 3. For in-water sediments, the ratios are less than 4. When comparisons are made within an exposure area for biota (which is the appropriate comparison, rather than Study Area-wide, given the heterogeneity in sources in PH), the vast majority of the ratios of the maximum EPCs to the mean are equal to or less than 2, and the remaining ratios are less than 4. EPA believes it is important that this information be presented in the main body of the risk characterization, as it shows that there are not major differences between risks calculated using the mean of the concentration data and those calculated using the maximum for individual exposure areas.*

LWG Resolution from 11-18-2010 Table:

> *[LWG Response: The BHHRA will be revised consistent with the comment.] EPA agrees with the response.*

LWG May 2, 2011 Response:

Additional text was included in this section to clarify the differences between the 95% UCL/maximum and mean concentrations.

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.2.6.3, page 131):

> *6.2.6.3 Using the Maximum Concentration to Represent Exposure*
>
> *For cases with less than five detected samples for a given analyte and exposure area, the sample size was not sufficient to calculate a 95% UCL on the mean concentration for an EPC, and the maximum concentration was used. This includes EPCs calculated to represent Study Area-wide exposure. Using maximum detected concentrations of infrequently detected contaminants to represent individual exposure areas, and especially Study Area-wide exposure, results in an extremely conservative estimate of risk for the Study Area. In general, use of 95% UCL on the mean concentrations or maximum concentrations provided a protective approach and likely resulted in overestimates of the actual risks, especially for ongoing, repeated, longterm exposures. Use of the maximum concentration to represent exposure occurred for all media, and occurred most frequently for the fish and shellfish consumption scenarios. Contaminants and exposure points for which the maximum detected concentration was used instead of a 95% UCL on the mean are presented in the exposure point concentration*

tables in Section 3. In some cases, the maximum concentration for a contaminant was anomalously high, and may not be representative of tissue concentrations resulting from exposure to CERCLA-related contamination within the Study Area.

Generally, the ratios between the maximum and minimum detected concentrations are less than 3. For in-water sediments, the ratios are less than 4. When comparisons are made within an exposure area for biota, the majority of the ratios of the 95% UCL/maximum EPCs to the mean are equal to or less than 2, and the remaining ratios are less than 4. A more in-depth analysis of scenarios for which using the maximum concentration to represent exposure significantly affected the result of the risk estimate, and consequently which chemicals were designated as contaminants potentially posing unacceptable risks for a scenario, is provided in Attachment F6.

The conservatism of using the maximum detected concentration as the EPC for exposure areas with less than 5 detected results impacts the conclusions of this BHHRA.

EPA Rational for Deficiency:

There is no rationale provided to adequately substantiate these findings, therefore, they are judgment and/or opinions which were agreed to be eliminated from the BHRRA.

14. **EPA July 16, 2010 comment #187 was not adequately incorporated.**

EPA July 16, 2010 comment #187 (Section 8.1.3, page 141-142):

The statement here that EPA does not recommend the use of data such as the N-qualified results overstates the actual recommendations presented in the guidance. In fact, EPA guidance recommends that when the identity of a chemical is uncertain, site history and other information should be used to establish whether there is reason to believe that the chemical may be present. As discussed in comments on page 112, Section 7.1.11, the list of chemicals presumptively identified in the Round 1 tissue samples should be compared to analytical results from sediment samples collected within the exposure areas related to the tissue samples (e.g., 1 mile for bass, 1 mile on either side of river for clams) as a means to determine whether there is reason to presume that chemicals for which the results are N-qualified are likely to be present in the tissue samples. If these analytes are not present in the sediment at concentrations that present a risk to human health, they may be excluded as PRGs.

LWG Resolution from 11-18-2010 Table:

EPA provided the following clarification: Prior to eliminating a chemical as a COC based on N-qualified data, the sediment data for the tissue COCs should be evaluated. If the N-qualified chemicals in tissue of small home range species (i.e., smallmouth bass, clams, and crayfish) result in a risk greater than 10^{-6} and are positively identified in sediment within the same exposure area, the chemical should be identified as a chemical potentially posing unacceptable risk.

LWG May 2, 2011 Response:

Chemicals identified as potentially posing unacceptable risk on the basis of N-qualified data only were not recommended for further evaluation.

EPA Rational for Deficiency:

The comment was directed towards the misquoting of EPA guidance, which was not fixed in the revised BHHRA, and asked for further analysis before eliminating the data, which doesn't seem to have been conducted in the revised BHHRA.

15. **EPA July 16, 2010 comment #195 was not adequately incorporated.**

EPA July 16, 2010 comment #195 (Attachment F2, Section 3.2, page 11-14):

Additional discussion and analysis are needed regarding the exclusion of the PCB congener data from the in-water sediment samples collected by the City of Portland for its outfall sediment investigation. These samples were excluded because of insufficient congener data (<100 PCB congeners for total PCBs, and <12 congeners for PCB TEQ) to calculate a summed total PCB congeners and total PCB TEQ. It is not clear if the 85 in-water sediment samples were excluded because the no congener analysis was conducted or because the detection limits were too high. Consistent with EPA guidance, non-detected data where the detection limit is greater than the maximum detected value should only be excluded when their inclusion results in the calculated EPC to be greater than the maximum detected concentration. In either instance, the overall effect on the in-water sediment COPC selection process and EPC calculations should be discussed.

LWG Resolution from 11-18-2010 Table:

[LWG Response: The LWG accepts the comment and will include additional language, information, and/or analyses in the revised BHHRA in addressing the comment.] EPA agrees with the response.

LWG May 2, 2011 Response:

Additional discussion was provided (the samples were excluded because the congener analyses were not conducted).

EPA Rational for Deficiency:

The draft BHHRA states that the data were excluded because of insufficient number of congeners, but does not state the rule nor does it address the last part of the comment, which asked for a discussion of the overall effect.

16. **EPA July 16, 2010 comment #209 was not adequately incorporated.**

EPA July 16, 2010 comment #209 (Attachment F5, Section 2.9, page 7):

This section is misleading and should be modified. The EPA document titled Cancer Dose-Response Assessment and Application to Environmental Mixtures (EPA/600/P–96/001F, September 1996) presents the rationale for the use of 3 different cancer slope factors for PCBs. Three slope factors are provided: 2 per mg/kg-day for high risk and persistence PCBs, such as Aroclor 1260 and 1254; 0.4 per mg/kg-day for low risk and persistence PCBs, such as Aroclor 1242; and 0.07 per mg/kg-day for lowest risk and persistence PCBs, such as Aroclor 1016. The high risk and persistence value should be used for those exposure pathways associated with environmental processes that tend to increase risk, including: food chain exposure; sediment or soil ingestion; dust or aerosol inhalation; dermal exposure (if an absorption factor has been applied); the presence of dioxin-like, tumor-promoting, or persistent congeners in other media; and early-life exposure (all pathways and mixtures). The low risk and persistence value should be used for those exposure pathways that tend to decrease risk, including: ingestion of water-soluble congeners, inhalation of evaporated congeners, and dermal exposure if no absorption factor has been applied. The lowest risk and persistence value should be used where congener or isomer analyses verify that congeners with more than four chlorines comprise less than one-half percent of total PCBs, suggesting that potency is best represented by the least potent tested mixture. All of the pathways assessed in the HHRA are included under the criteria for use of the high risk and persistence cancer slope factor of 2 per mg/kg-day. Even for scenarios where adults only (not children) ingest water, the lower cancer slope factor (0.4 per mg/kg-day) should not be used, as risks are calculated using surface water data that would contain both water soluble congeners and those found in water-borne colloidal material and particulate matter.

LWG Resolution from 11-18-2010 Table:

[LWG Response: The BHHRA will be revised consistent with the comment.] EPA agrees with the response.

LWG May 2, 2011 Response:

Revised per comment.

EPA Rational for Deficiency:

The point of comment 209 was that a) the exposure pathways evaluated in the risk assessment were those for which use of the "high risk and persistence" SF was appropriate. Therefore, the alleged "uncertainty" discussed was in no way relevant to the Portland Harbor risk assessment. Rather than present any specific information justifying any specific instance where the lowest risk and persistence slope factor may have been appropriate, the LWG simply added the text from the comment describing why the whole analysis was inappropriate in the first place, without deleting the offending analysis. The language, being unsubstantiated, was judgmental or opinionated which was to be deleted from the BHHRA.

17. EPA December 23, 2009 and July 16, 2010 general comment #1 were not adequately incorporated.

EPA December 23, 2009:

Inappropriate Statements Regarding Fish Ingestion Rates

The BHHRA makes numerous statements throughout the document that question the fish consumption rates used to evaluate the risks to human health. For example, the three main rates are referred to as high (17.5 g/day), higher (73 g/day), and highest (142 g/day). EPA disagrees with this characterization. The EPA rate of 17.5 g/day (two 8-oz meals per month) is based on the 90th percentile of the general population, which includes non-consumers of fish. The 90th percentile for fish consumers is much higher (200 g/day). EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. It is not an unreasonable rate, and should not be referred to as a "high" ingestion rate, but rather as a "low" ingestion rate.

The rate of 142 g/day used as the highest rate for non-tribal fishers in this risk assessment is the 99th percentile for consumers and non-consumers from the same USDA study; the consumption rate for consumers only from this study is 506 g/day. The ingestion rate of 142 g/day was used by EPA in developing its Ambient Water Quality Criteria for consumers who obtain much of their daily protein from fish; therefore, it is appropriate to use this value as a "high" ingestion rate for this risk assessment. It should be kept in mind that the rate of 142 g/day does not truly describe subsistence consumption as a "subsistence"

fish consumer would obtain almost all of their protein from fish. The more appropriate rate for subsistence fishers may be closer to the 506 g/day value which is the 99th percentile value for consumers only in the USDA study. This is supported by the fish consumption study of the Suquamish Tribe in Puget Sound whose 90% biota consumption rate is over 500 g/day. The consumption rate of 142 g/person/day was used to represent high frequency non-tribal fishers in this risk assessment. For subsistence fish consumers, who could represent an important population in PH, using 506 g/day as an approximate subsistence value, only about 28% (142 g/day divided by 506 g/day) of total fish consumption would have to come from the LWR in order for a consumption rate of 142 g/person/day and the upper range risks estimated in the HHRA to apply.

For the third non-tribal adult fish consumption rate used in this risk assessment, 73 g/day, data from the Columbia Slough Study was used. The possible uncertainties in this study and in the consumption rates derived from it rate are appropriately discussed in the BHHRA. The BHHRA discussion and the data from the USDA study support use of a fish consumption value of 74 g/day as "medium" consumption rate, not a "higher" consumption rate.

The arguments concerning uncertainties in fish ingestion rates provided in the HHRA are not compelling. Further, EPA believes that the body of information available regarding fish consumption rates both nationally and locally makes it clear that the fish ingestion rates used in the BHHRA appropriately address a range of exposures that might occur for consumers of locally caught fish. Text throughout the document should be revised to indicate the nature of these risk estimates, as indicated above, and appropriate text substituted to acknowledge the need to protect high consuming fish populations and discuss fish ingestion rates in that context.

EPA July 16, 2010 general comment #1:

The draft Portland Harbor Baseline Human Health Risk Assessment (BHHRA) includes numerous statements regarding the fish consumption rates used to evaluate the risks to human health. The three primary non-tribal fish ingestion rates used in the draft BHHRA are characterized as high (17.5 grams per day [g/day]), higher (73 g/day), and highest (142 g/day). EPA disagrees with this characterization, believes them to be misleading, and believes that significantly higher ingestion rates may be appropriate to represent different local and ethnic populations that rely on fishing as part of their culture and/or as a substantial food source. As such, the three ingestion rates presented in the BHHRA should be characterized as low, moderate, and high.

The rate of 17.5 g/day (equivalent to two 8-ounce meals per month) is based on the 90th percentile rate for uncooked freshwater and estuarine finfish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002b, data from USDA CSFII Study). The 90th percentile for fish consumers only from this USDA study is much higher, at 200 g/day. EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. It is not an unreasonable rate, and should not be referred to as a high ingestion rate, but rather as a low ingestion rate.

A non-tribal adult fish consumption rate of 73 g/day was used in this risk assessment based on data from the Columbia Slough. The possible uncertainties associated with the consumption rates derived from this study are appropriately discussed in the BHHRA. The BHHRA discussion and the data from the USDA study support use of a fish consumption value of 73 g/day as moderate consumption rate, not a higher consumption rate.

The rate of 142 g/day used as the highest rate for non-tribal fishers in the draft BHHRA is the 99th percentile for consumers and non-consumers from the same USDA study; the consumption rate for consumers only from this study is 506 g/day. The ingestion rate of 142 g/day is used by EPA in developing Ambient Water Quality Criteria (AWQC) for consumers who obtain much of their daily protein from fish. The consumption rate of 142 g/person/day was selected in the BHHRA to represent high-frequency, non-tribal fishers, and represents an appropriate "high" ingestion rate for the Portland Harbor (PH) risk assessment.

Overall, the arguments concerning uncertainties in fish ingestion rates provided in the HHRA are not compelling. Further, EPA believes that the body of information available regarding fish consumption rates, both nationally and locally, makes it clear that the fish ingestion rates used in the BHHRA appropriately address a range of exposures that might occur for consumers of locally caught fish. Please revise text throughout the document to indicate the nature of these risk estimates, as indicated above, and substitute appropriate text to acknowledge the need to protect high consuming fish populations and discuss fish ingestion rates in that context.

LWG Resolution from 9-15-2010 Table:

The LWG recognizes that the ingestion rates from the USDA CSFII Study are for both consumers and non-consumers; however, the rates used in the draft BHHRA are equal to the 90th and 99th percentiles, which are considered upper-bound exposures per RAGS A: "If statistical data are available for a contact rate, use the 95th percentile value for this variable. (In this case and throughout this

chapter, the 90th percentile value can be used if the 95th percentile value is not available.)" Furthermore, the draft BHHRA did not consider the fraction of fish consumed from the site, did not account for reductions due to preparation and/or cooking methods, and assumed consumption of resident fish only (i.e., no anadromous fish such as salmon). Therefore, applying the 90th and 99th percentile ingestion rates for all fish and shellfish consumption combined in a national diet study to consumption of resident fish only exclusively from Portland Harbor is an uncertainty, as discussed in the draft BHHRA.

As discussed at the September 9th meeting, ingestion rates will be presented in the revised BHHRA as the numeric rates (i.e., grams per day or meals per month) and the source of the rates will be presented, consistent with the text in the Programmatic Work Plan. Characterization or descriptors of the ingestion rate (e.g., "low", "high") will not be included in the revised BHHRA.

LWG May 2, 2011 Response:

As discussed at the September 9, 2010 meeting, ingestion rates are presented in the revised BHHRA as the numeric rates (i.e., grams per day or meals per month) and the source of the rates is presented, consistent with the text in the Programmatic Work Plan. Characterization or descriptors of the ingestion rate (e.g., "low", "high") are not included in the revised BHHRA.

Basis for EPA determination:

The Superfund Human Health Risk Assessment guidance (RAGS part A, Chapter 6) defines the Chronic Daily Intake (CDI) as *exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a long period of time (as a Superfund program guideline, seven years to a lifetime)* and the Lifetime Average Daily Intake as *exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a lifetime*. LWG agreed to not present these risks in a judgmental or opinionated fashion. While the LWG stated that these are meals per month which was agreed to, the LWG kept opinionated language, such as, "same rate every day of every year for 70 years." [sic Section 3.5.1.6.3, page 66, Section 6.2.5.1, page 124, Section 6.2.5.2, page 125, and Section 6.2.5.3, page 128 as well as the statement made in Section 5.2.5.2.1, page 98 "…every month of the year exclusively of fish caught within the Study Area."

EXHIBIT 4

From: Wyatt, Robert [mailto:rjw@nwnatural.com]
Sent: Thursday, September 06, 2012 5:15 PM
To: Jennifer Woronets
Subject: FW: follow up from this morning

From: Cami Grandinetti [Grandinetti.Cami@epamail.epa.gov]
Sent: Thursday, September 06, 2012 5:12 PM
To: Wyatt, Robert
Subject: follow up from this morning

Bob, I apologize for not getting to this until the end of the day so I'll delay no more:
First question-- do you have all the issues EPA believes put LWG in non-compliance? Yes, you have all the issues. Of course if we generate new documents, there may be new issues but that would be different.

Second question--What is the process of removing the non-compliance letter? This one is harder to answer but in general, we've said that if we can come to agreement on the Risk Assessment, non-compliance can be taken away. I think we need to discuss in greater detail what/when it means we've come to agreement on the Risk Assessment. Let's perhaps discuss on Monday.

Gotta run--email if you have any questions.

Cami Grandinetti
Program Manager, Remedial Cleanup Program
USEPA
(206) 553-8696 (desk)
(206) 390-8890 (cell)
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1200 6th Avenue, Suite 900
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Seattle, Wa. 98101

EXHIBIT 5

LWG
LOWER WILLAMETTE GROUP

Chairperson: Bob Wyatt, NW Natural
Treasurer: Fred Wolf, Legacy Site Services for Arkema

Via Hand Delivery

October 24, 2012

Daniel Opalski
Director, Office of Environmental Cleanup (ECL)
U.S. Environmental Protection Agency, Region 10
1200 Sixth Avenue, Mail Code: ECL-117
Seattle, WA 98101

Re: Lower Willamette Group Reply to EPA Submission
Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution
Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket No: CERCLA-10-2001-0240

Dear Mr. Opalski:

EPA's decision, without warning, to completely rewrite the Portland Harbor Baseline Human Health Risk Assessment (BHHRA) to "correct" agreements EPA made with the LWG over several years about the contents of the BHHRA and to find the LWG in violation of the Consent Order is sufficient evidence that the working relationship between EPA and the LWG is broken. The fact that EPA declined to identify to the LWG the specific grounds for the alleged violations for nearly five weeks while it attempted to persuade the LWG to accept its wholesale rewrite of the BHHRA makes this a watershed moment for cooperating parties working with EPA at the Portland Harbor site and beyond. Whether or not EPA's view that "the process actually worked as the AOC was designed"[1] is legally correct, dressing up EPA's change of mind as the performing parties' failure to meet their obligations is not going to get Portland Harbor, or any other site, cleaned up.

We disagree that the Consent Order was designed to support EPA in lulling the Lower Willamette Group into "perceived agreements" just to "keep the RI/FS and risk assessment moving forward."[2] We disagree that the Consent Order was designed to support EPA in seeking stipulated penalties because the LWG supposedly failed to incorporate comments that EPA labeled as "non-directed" when it made them but that EPA now claims we should have understood were actually "directions for change." We think the fact that, out of 223 comments on the draft BHHRA, EPA has complained about only16 LWG responses, all of which are

[1] EPA October 12, 2012 Response, p. 23.
[2] EPA October 12, 2012 Response, p. 22.

unrelated to EPA's stated reasons for rewriting the BHHRA, tells the whole story.[3] We reiterate that the LWG's May 2011 draft final BHHRA used sound science to assess potential risks to human health at Portland Harbor, and EPA has not questioned any of the LWG's calculations or principal conclusions.

But even if the Consent Order gives EPA the unfettered discretion EPA claims, EPA's exercise of that discretion against the LWG in such a punitive manner makes absolutely no sense. Of the 144 potentially responsible parties EPA has thus far identified at Portland Harbor, only the 14 LWG members have made any meaningful attempt to cooperate with EPA on the remedial investigation and feasibility study. We don't understand why EPA thinks it is important to prosecute an enforcement action against the LWG for including the word "generally" in a sentence summarizing the results of a fish consumption survey (text EPA didn't bother to change in its own version of the BHHRA).[4] However, the message EPA is sending to parties who refuse to participate is crystal clear: it's better to stonewall than to cooperate.

To us, it seems that EPA has a clear interest in honoring shared expectations with settling parties and in initiating open dialogue with those parties when problems arise. The significant progress toward agreement on the BHHRA during the informal negotiation period demonstrates that the LWG would have cooperated with EPA in making adjustments to the BHHRA that EPA now believes are necessary. Finalizing the BHHRA through agreement would have been consistent with more than a decade of collaborative effort on the Portland Harbor RI/FS. Vacations and scheduling issues during the informal negotiation period made it challenging to resolve all areas of disagreement during August, but if EPA had been willing to continue talking, we believe the remaining issues would have been resolved in less time than it will take to complete this formal dispute resolution process. EPA's willingness to resolve these issues outside the enforcement context would have conveyed to the dozens of other responsible parties who will ultimately be asked to participate in the cleanup that EPA will work cooperatively with settling parties.

This process is broken. We ask you to drop the enforcement action and encourage EPA staff to move forward in a way that builds trust, comports with baseline due process, and is fundamentally fair to the parties that have spent nearly $100 million on the RI/FS. The LWG shares EPA's priority of protecting human health and the environment through the identification of protective remedies supported by the community. We are part of the solution, not the problem.

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[3] That these complaints include, for example, the LWG's failure to include information in Tables 5-199 through 5-203 that EPA's comment specifically told the LWG to include in Table 5-204 would be comical if the consequences weren't so serious.

[4] *See, e.g.*, Interim Policy on Settlement of CERCLA Section 106(b)(1) Penalty Claims and Section 107(c)(3) Punitive Damages Claims for Noncompliance with Administrative Orders (EPA, September 30, 1997) ("Issuance of this policy is part of an ongoing effort to make the Superfund program fairer for the parties that take responsibility for cleaning up Superfund sites by taking appropriate enforcement action against those parties who are liable and who fail to participate in the cleanup.")

I. The LWG has not violated the Consent Order.

The LWG submitted a technically sound, compliant BHHRA to EPA that was both consistent with the NCP and EPA's previous direction. The most important thing to know about EPA's finding that the LWG violated the Consent Order is that EPA does not rely on even one of the 17 violations it alleged as a reason for its complete rewrite of the BHHRA.[5] Instead, EPA admits that it modified the BHHRA because "the Remedial Project Managers (RPMs) at times through the process may have agreed to a path forward demanded by the Respondents to keep the RI/FS and risk assessment moving forward. However, at the time the full ramifications and consequences of those agreements became apparent in the second draft BHHRA, a correction in course was needed and EPA modified the text of the BHHRA to make those corrections."[6] EPA's determination that the LWG violated the Consent Order is, as EPA says, "separate and distinct"[7] from that "correction in course."

EPA's view is that it can take enforcement action under the Consent Order if, in EPA's sole discretion, it determines that the LWG has failed to "fully" incorporate any EPA comment into a revised deliverable. Although EPA's October 12 response itself states that the June 22 notice of noncompliance was issued because the May 2011 draft final BHHRA "did not fully reflect EPA's directions for changes,"[8] what EPA actually argues in its brief is that comments the EPA identified to the LWG as "non-directed"[9] were in fact "directions for changes."[10] In other words, EPA is saying that although during years of discussions, it has made a distinction between which of its comments were directive and which were not, the LWG should have known that, in the end, all were directive and all would be enforced equally. As an enforcement policy, this position violates the express terms of the Consent Order and raises serious due process questions. And it unquestionably undermines EPA's express commitment to "work cooperatively with settling PRPs to use limited Federal and PRP resources even more effectively to achieve timely and protective site cleanups."[11]

The Consent Order plainly provides that EPA can seek penalties – precisely what EPA is threatening here – only when a revised submittal does not fully reflect EPA's "directions for changes."[12] We have always understood that this is the specific purpose for EPA's practice of

[5] EPA's explanation for its finding of violation has been in flux. EPA's June 22, 2012 notice of noncompliance to the LWG (Tab 16) identified four alleged "deficiencies" and concluded that the LWG had "failed to perform in accordance with the requirements of the Order by failing to fully correct all deficiencies...." On July 27, 2012, EPA advised the LWG that those four "deficiencies" were not the basis for the notice of noncompliance and provided the LWG with a list of 17 other alleged violations (Tab 22). EPA withdrew its complaint about item 11 from the July 27 list in its October 12, 2012 Response (Exhibit 6, page 20).

[6] EPA October 12, 2012 Response, p. 22.

[7] *Id.* at p. 4.

[8] EPA October 12, 2012 Response, p. 4.

[9] EPA September 22, 2010 letter (Tab 10) to Wyatt, p. 2.

[10] EPA October 12, 2012 Response, p. 8 ("'directions for changes' ... logically must be read as an abbreviated restatement of 'correct all deficiencies and incorporate and integrate all information and comments supplied by EPA.'").

[11] Interim Guidance on Implementing the Superfund Administrative Reform on PRP Oversight (EPA, May 17, 2001).

[12] Consent Order, §IX.4.

identifying comments as "directed change"[13] or "EPA direction."[14] Indeed, that is precisely how both parties have outwardly operated over the course of the last ten years. If we are equally at risk for guessing wrong about how to "fully" incorporate any EPA comment no matter how characterized by the agency, why has EPA called to our attention "directed" comments which "will be incorporated" as a priority over comments EPA refers to as "non-directed"?[15]

When EPA provides comments on an LWG document, §IX.1 of the Consent Order requires EPA to meet with the LWG "in an effort to resolve disputes" on EPA comments, modifications, and directed changes.[16] Then, "at EPA's discretion" the LWG must "fully incorporate and integrate all information and comments" supplied by EPA. The "at EPA's discretion" language has no meaning in the absence of EPA identifying to the LWG those changes the LWG must make to produce an acceptable document. As with any agreement, the parties' course of dealing under the Consent Order over many years is persuasive evidence of their joint interpretation of the Order. *See Yogman v. Parrot*, 325 Or. 358, 364, 937 P.2d 1019 (1997). As EPA notes in footnote 11 of the October 12 response, EPA and the LWG meet to attempt to resolve EPA comments, and EPA often "directs" changes where the parties fail to reach agreement on the resolution of a particular comment. Again, this is how EPA and the LWG have actually operated for more than ten years: Indeed, what possible meaning could "directed changes" have if it is not to distinguish directive comments from those that are not directive?

Even if EPA is correct that all comments are equal, regardless of how EPA describes them to us, we must still be able to understand what it is EPA expects us to do with the comment. Due process requires that EPA provide the LWG fair notice of what it needs to do to comply with the Consent Order.

> "The Due Process Clause of the Fifth Amendment to the United States Constitution prohibits a federal agency from enforcing an interpretation of a regulation that is not "ascertainably certain." *General Elec. Co. v. United States EPA*, 53 F.3d 1324, 1328 (D.C.Cir.1995). A regulatory agency supplies fair notice "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform...." *Id.* at 1329. However, where an agency "provide[s] no pre-enforcement warning, effectively deciding to use a citation [or punishment] as the

[13] EPA July 16, 2010 comments on the September 2009 draft BHHRA (Tab 8). *See also* EPA July 15, 2011 comments on FS Key Elements Check-in Meeting, attached at Tab 50 ("EPA is providing most of the attached comments as directed comments in order to expedite completion of the draft FS report, and to emphasize that these changes are required to produce a draft FS meeting EPA's expectations....").
[14] EPA January 15, 2008 comments on the Comprehensive Round 2 Site Characterization and Data Gaps Analysis Report (Tab 28) ("Category 4: These comments represent EPA direction on the data analysis. EPA expects these changes will be incorporated.")
[15] EPA September 22, 2010 (Tab 10) letter to Wyatt, p. 2.
[16] Notwithstanding EPA's discussion later about the importance of uniform documents and model orders, the "EPA will meet with Respondents in an effort to resolve disputes" language was added to the Consent Order by the LWG and accepted by EPA. *See* Dost email to E McKenna, February 28, 2001, attached at Tab 51.

> initial means for a announcing a particular interpretation," constitutional questions are raised about fair notice to regulated parties. *Id.*[17]

EPA's practice of identifying "directed" and "non-directed" comments over several years has led the LWG to understand that EPA's interpretation of "directed" and "non-directed" is the complete opposite of what it is positing now. Not only did EPA not provide the LWG with "fair notice" that EPA considers all comments equal from an enforcement standpoint, but it took positions that indicated that there was absolutely a distinction between directed and non-directed comments. And even at the level of the comment itself, EPA's direction, for example, that a revision must be made "in the next revision or the final version of the BHHRA as appropriate" does not provide "fair notice" that EPA will consider the LWG in violation of the Consent Order for choosing to make the revision in the final.[18] EPA's direction to include certain information in Table 5-204 does not provide "fair notice" that EPA will consider the LWG in violation of the Consent Order for not also including the information in Tables 5-199 through 5-203.[19]

On page 7 of its October 12 response, EPA admits that it did not provide the LWG with the alleged bases for its finding of non-compliance for over a month after EPA served the LWG with its allegation that the LWG had violated the order, and only after the LWG timely invoked its right to dispute that allegation. Bedrock principles of due process, 40 C.F.R. §22.14(c)(3), and Section 555e of the Administrative Procedures Act, all require a concise statement of the factual basis or grounds for each violation alleged. That EPA declared the LWG in noncompliance without assembling and providing the factual bases for its declaration speaks volumes about EPA's casual attitude toward taking enforcement action against the LWG. In fact, even after providing its compilation of the 17 alleged violations in late July, EPA still communicated to the LWG that these were not necessarily comprehensive and that there might be more.[20] Only later did it decide this list was complete. This practice is also a violation of due process.

Finally, we ask you to look closely at both the significance of the alleged violations and the distance by which EPA alleges we missed the mark in our response. The LWG submitted a sound technical and legal document, consistent with EPA previous revisions and that complies with the NCP and EPA guidance. Out of 223 EPA comments on the May 2011 draft final BHHRA, EPA was able to identify only 17 – now 16 – comments or partial comments where it could manufacture some level of grievance with the LWG's response. As described in Table 3 to the LWG's September 21 opening submission, the LWG addressed all EPA comments in good faith consistent with the agreements reached on EPA comments on the 2009 draft BHRHA. None of the 17 comments relates to the significant revisions EPA has now decided the BHHRA requires. This is not the kind of "substantial noncompliance" on which EPA typically focuses its

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[17] *United States v. Hadjuk*, 2005 WL 3237308, (D. Colo 2005). *See also United States v. Approximately 64,695 Pounds of Shark Fins*, 520 F.3d 976, 980 (9th Cir. 2008); *United States v. Hoechst Celanese Corporation*, 964 F. Supp. 967, 979-80 (D. S.C. 1996), *reversed in part on other grounds*, 128 F.3d 216 (4th Cir. 1997).
[18] *See* EPA Basis for Noncompliance (Tab 22), #1.
[19] *Id. See also* EPA October 12, 2012 Response, Exhibit 6.
[20] Cora July 27, 2012 email to Parkinson, attached at Tab 52.

enforcement resources;[21] it is, in fact, of so little consequence that in most cases EPA did not even bother to make in its "directed" version the revision on which it bases its enforcement action. A short summary of the alleged violations shows the trivial nature of EPA's complaints about the LWG's work:

[21] See Ensuring Potentially Responsible Party Compliance with CERCLA Obligations (EPA, November 27, 1996); Guidance on Determining and Tracking Substantial Noncompliance with CERCLA Enforcement Instruments in CERCLIS (EPA, August 24, 2009).

	EPA comment	EPA description of comment	LWG revision based on comment resolution	Basis for EPA noncompliance determination	Did EPA make the revision identified in its July 27, 2012 "basis" memo in its June 22, 2012 directed redline?
1	a) Identify PBDE in Table 5-189 for further evaluation b) Discuss PBDE in risk characterization section of revised or final BHHRA	Directed change	a) PBDE identified in Table 5-204 (formerly 5-187 – the October 2009 draft BHHRA had no Table 5-189) b) PBDE to be discussed in risk characterization section of final BHHRA	a) PBDE should have been included in Tables 5-199 through 5-203. b) PBDE should have been included in risk characterization section of revised BHHRA.	a) No b) No
2	Throughout the text, figures, tables and maps, the phrase "RME Exposure" should be used in place of 95% UCL or Maximum"	Revise, clarify	EPCs were described in a factual manner in the BHHRA (i e. the EPC was identified as the mean, 95% UCL, or maximum). The terms RME and CT were not used in reference to the EPCs. The titles of the EPC tables in Section 3 (with the exception of Table 3-4, which was an oversight) and risk tables in Section 5 were revised as well, with the exception of the fish consumption risk tables per the prior agreement to not use RME/CT in reference to the fish consumption scenarios	Tables should have been modified to identify RME and CT for EPCs and for fish consumption risks.. Although EPA agreed that EPCs would not be discussed as RME or CT, EPA didn't understand that this agreement applied to the text as well as the tables.	Partially; however EPA's revisions do not define the EPCs used to evaluate the RME and CT
3	Modify text to read. "Although fishers normally fish and/or collect those resources that are available in their area, it is not known to what extent fishers would substitute alternative local types of shellfish."	Directed change	"It is not known to what extent fishers substitute alternative local types of shellfish."	LWG did not include "although fishers normally fish and/or collect those resources that are available in their area," which EPA believes is a factual statement rather than a statement of opinion or judgment	No. EPA retains LWG text exactly in §6.2.4.3.
4	Delete 2 sentences: "Uncertainty or variability factors, which typically range from two to three orders of magnitude (100 to 1000 times), are often used by EPA in deriving toxicity values for human health given the uncertainties in the toxicological data. As a result actual risks within the Study Area could be lower than the potential risk estimates calculated in the BHHRA."	Revise	"Modifying factors, which typically range from two to three orders of magnitude (100 to 1000 times), are often used by EPA in deriving toxicity values for human health given the level of confidence in the toxicological data, the intera-species differences (i.e. animal to human) and the inter-species differences to account for sensitive human subpopulations."	The revised text fails to clarify that modifying factors aren't used in the derivation of slope factors.	Yes (only because entire executive summary deleted)
5	The October 2009 BHHRA suggests that the report is different from other risk assessments because EPA directed the use of conservative assumptions. This is typical and consistent with guidance.	Revise	"Therefore, the results of the BHHRA have a margin of conservatism built into the risk conclusions consistent with EPA guidance (1989)"	EPA disagrees that the results of the BHHRA have a margin of conservatism built into the risk conclusions	Yes
6	Explain why only one of the surface water samples (W020) from Swan Island Lagoon was used for COPC screening for transients and recreational beach exposures and for the domestic water source.	Clarify	"For transients and beach users, COPCs were selected from surface water samples taken from areas where direct contact with transient or beach users could occur, including both single point sampling stations where vertically integrated samples were collected and transect samples. This included one sample from Swan Island Lagoon."	LWG did not explain, and EPA does not know, why samples W021 and W035 were not used.[22]	No. Discussion of surface water data set used for COPC screening deleted.
7	Change "suggest" to "show" in a sentence describing a fish consumption survey	Revise	"The results of the survey show that tribal members surveyed generally have higher fish ingestion rates than the general public."	The LWG's language inappropriately qualifies the survey results inconsistent with EPA's provided language when used in conjunction with other language in the LWG's draft of Section 3.	No. EPA sentence in §3.2 1.7 reads, "The results of the survey show that tribal members surveyed generally consume more fish than the general public."
8	Text needs to identify that arsenic occurs naturally and describe the degree to which background arsenic concentrations contribute to risk.	Revise, clarify	Text revised to state that arsenic occurs naturally and to identify beaches at which arsenic concentrations are greater than background levels. These beaches are shown on Maps 5-2-1 and 5-2-2.	"We made a comment and their response went the wrong direction."	No. EPA deleted all discussion in §5 of potential risk related to background concentrations in arsenic in sediment and water.[23]

[22] Note that RI Map 5.3-1a clearly identifies locations of vertically integrated samples and identified W020 as the only such sample in Swan Island Lagoon. EPA and the LWG agreed to use integrated samples to identify COPCs for these exposure scenarios in the April 30, 2008 RI/RA issue resolution table, attached to this Reply at Tab 53.

[23] EPA's October 12, 2012 Response states that "EPA deleted all discussion of potential risk related to background concentrations of arsenic because it was inappropriately presented." Exhibit 6, p. 15. But it's clear from the June 22 EPA redline that EPA actually did intend to discuss risks from background arsenic: "Risks from background concentrations of arsenic in beach sediment and surface water are discussed in section 5 of the BHHRA." EPA June 22 directed redline, §6 4.3.

9	Provide supporting information for comparison of depurated and undepurated clam tissue, and state that undepurated clam data provides information only on 5 sampling locations, all of which were on the edges of the site rather than in areas with particularly high cPAH concentrations.	Issue	"Depurated clam tissue samples were collected from five locations at the northern and southern edges of the Study Area, while undepurated clam tissue samples were collected from 22 locations throughout the Study Area." Concentrations of COPCs in depurated and undepurated tissue samples were provided in a table in Attachment F6.	Depurated clam tissue concentrations should not have been compared with non-depurated clam tissue concentrations.	No. EPA deleted any reference to or discussion of depurated clams from §5
10.	Delete sentence "In a deterministic risk assessment multiple conservative assumptions compound to result in an estimate of risk that can be many times (or orders of magnitude) greater than the likely actual risk posed by a particular site."	Revise	Text revised to state "In a deterministic risk assessment, conservative assumptions can compound to result in an estimate of risk that is at the upper end of the probable risk range."	LWG should have provided justification in support of "compounding" statement and did not and therefore the statement is a judgment or opinion.	Partially. EPA's text in Section 7.0 makes same point "The cumulative effect of these assumptions can result in an analysis having an overall conservativeness greater than the individual components."
11.	Withdrawn by EPA October 12 response				
12.	Database for COPCs in depurated clam tissue was limited to 5 of 22 samples, and the five samples are from the northern and southern stretches from the river and may not be representative of conditions from entire length of site and risk assessment should discuss uncertainty associated with same.	Issue	Text in uncertainty section revised to note that depurated samples were collected at only 5 stations at the edtes of the site and reference tables comparing depurated and undepurated tissue concentrations.	The LWG did not statistically prove that depurated clam tissue was representative of conditions throughout the study area.	No. EPA text in §6.1.4 is virtually identical.
13.	Present information related to the ratios between maximum and minimum concentration values in the main body of the risk characterization, as it shows that there are not major differences between risks calculated using the mean of the concentration data and those calculated using the maximum for individual exposure areas.	Clarify	"Generally, the ratios between the maximum and minimum detected concentrations are less than 3. For in-water sediments, the ratios are less than 4. When comparisons are made within an exposure area for biota, the majority of the ratios of the 95% UCL/maximum EPCs to the mean are equal to or less than 2, and the remaining ratios are less than 4.	Other text not identified by the original comment contains judgment or opinions	Partially. The language added by the LWG in §6.2.5.3 was retained. EPA deleted another sentence.
14.	Do not automatically disqualify N-qualified data.	Issue	No data were eliminated from the identification of whether a chemical potentially poses unacceptable risk on the basis of N-qualified results	The comment was directed towards the misquoting of EPA guidance, which was not fixed in the revised BHHRA, and asked for further analysis before eliminating the data, which doesn't seem to have been conducted in the revised BHHRA.	Partially. EPA slightly modified the LWG's discussion of guidance in §7.1.1, but the LWG never eliminated any data on this basis.
15.	Additional discussion and analysis needed for excluding PCB congener data from City of Portland outfall sediment investigation	Issue.	"This table shows 85 in-water samples for which Total PCB congeners were not calculated because of limited number of analytical results from the City of Portland outfall sediment investigation. These samples were analyzed for a limited number of congeners that did not meet the minimum number of PCB congeners required to compute a sum.	Draft BHHRA does not state the rule for excluding the data, nor does it discuss the overall effect of the exclusion	No. EPA deleted all discussion about the City of Portland Investigation.
16.	Use of high risk and persistence value cancer slope factors	Issue	Comment requested modification of Section 2.9 of Attachment F6. LWG modified the section using the exact language EPA provided in the comment. The comment did not request or instruct deletion of any text.	Comment required modification of language, not insertion of EPA language.	No. (Although Exhibit 6 to EPA's October 12 response suggests that this will be a future EPA comment or revision to the BHHRA.)
17.	Fish ingestion rates (g/day) should not be characterized as "high," "higher" and "highest." Text should be clear that fish ingestion rates in the BHHRA appropriately address a range of exposures and protect high fish consuming populations.	Directed	Text of the draft final BHHRA was revised to describe ingestion rates numerically (g/day) rather than characterizing the rates as "high" or "low."	The LWG used opinionated language, such as "same rate every day of every year for 70 years" in five places in the BHHRA to describe the duration of exposure through fish consumption.	Yes.

EPA's October 12, 2012 response implies that its enforcement action against the LWG is, at least at this point, not significant, because "in the future ... agency discretion may be applied in determining whether to assess stipulated penalties."[24] However, the finding that the LWG violated the AOC carries with it a "black mark" that causes reputational harm and potential adverse effects in subsequent proceedings. (Straus Communications, Inc. v. FCC, 530 F2d 1001, 1006 (D.C. Cir 2006). As EPA well knows, the mere finding of noncompliance has the potential to create real problems for LWG members, including possibly increasing the difficulty and expense of recovering RI/FS costs from insurers or other PRPs and the potential trigger of regulatory or financial disclosure requirements. EPA's action has already resulted in highly negative media coverage for the LWG (including a story featuring an interview given by one of the EPA RPMs during the informal negotiation period).

On July 17, 2012, six days before the LWG initiated formal dispute resolution, one of EPA's RPMs contacted the LWG's project manager, Bob Wyatt, and offered to withdraw the notice of noncompliance if the LWG would agree not to dispute EPA's direction to accept all of its revisions to the May 2011 BHHRA. Although EPA insists that it is not "being coercive," just "using its enforcement authorities,"[25] it is very difficult to view EPA's relentless quest to find "even one" discrepancy between EPA's comments on the BHHRA and the May 2011 draft final BHHRA as anything but an attempt to leverage the LWG into quietly acquiescing in EPA's decision to set aside three years of work on the BHHRA and start over. Fortunately for all, the LWG and EPA worked together to improve upon the EPA's June 2012 directed redline, and, as a result of the very kind of collaborative process that EPA and the LWG have historically used, the September 2012 version is much more accurate than the June 2012 directed redline..[26]

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[24] EPA October 12, 2012 Response, p. 9.

[25] EPA October 12, 2012 Response, p. 6.

[26] EPA's June 2012 directed redline of the BHHRA was replete with errors and misstatements. Many of these errors and misstatements are identified in Tables 1 and 2 to the LWG's September 21 Opening Submission (noted as "1 – Technical Inaccuracy"). An egregious example is EPA definition of the Study Area in the June 2012 directed redline as RM 0.8 to RM 12.2. The EPA approved definition of the Study Area for the Remedial Investigation is RM 1.9 to RM 11.8. With no explanation, EPA added 1.5 miles to the Study Area. A second example is that sections 5 and 7 of EPA's June 2012 directed redline mischaracterized the risk posed by aldrin, arsenic, DDx, and dioxins/furans. A third example is that section 3 of the June 2012 directed redline incorrectly described how risks to children and infants were calculated. Other numerous examples are identified in Tables 1 and 2. EPA and the LWG worked together to resolve these errors during the informal negotiation period. Any minor errors in the LWG's May 2011 draft final BHHRA could have similarly been easily resolved through conversation, had EPA chosen to initiate it. The fact that the exemplary standard imposed on the LWG apparently does not apply to EPA's work product underscores the LWG's assertion that EPA's handling of this matter was arbitrary and capricious.

II. EPA should work with the LWG to finalize the BHHRA.

A. EPA's Reasonable Maximum Exposure is still unreasonable and inconsistent with guidance and merits 60 Days of further discussion.

EPA is asking you to adopt its Reasonable Maximum Exposure (RME) proposal without any further refinement or discussion. That would be a mistake. EPA's RME proposal was hastily developed, it still has significant flaws, and EPA has not allowed sufficient time to discuss it with the LWG. EPA made a decision in 2004 not to include an RME for fish consumption, and then in June 2012 decided a "course correction" was needed and designated over 108 RMEs without any discussion with the LWG.[27] The LWG is simply asking ~~the~~ you to allow 60 days to refine the RME approach to ensure that the BHHRA, and ultimately the cleanup plan, is technically and legally sound based on the information and data collected about the Site over the past eight years.

After reviewing LWG's objections to the June "course correction," EPA revised its RMEs. Specifically, EPA has acknowledged that the recreational fisher RME should use fillet with skin, not whole body, and that both the recreational and subsistence fisher RMEs should be based on a multi-species diet of resident fish, rather than one single species. While EPA's adjustments are a step in the right direction, significant issues still must be addressed to produce a technically defensible BHHRA.

There are two fundamental problems that remain in EPA's newest RME proposal, which is contained in EPA's October 12 response. First, EPA evaluates each exposure factor in isolation in direct contradiction of the guidance. Risk Assessment Guidance for Superfund (RAGS) provides that the RME scenario for each pathway is developed by combining a mix of upper bound and mid-range exposure factors.[28] For example, one cannot select the exposure area without considering the consumption rate, type of species consumed, and time period of exposure. However, for the RME here, EPA has selected each exposure factor without evaluating its relationship to other exposure factors, thereby creating RMEs that are unlikely to occur. The second problem is that while EPA admits there are concerns over the validity of certain assumptions it makes, it summarily dismisses those concerns because it believes a change to address them would have minimal impact on the baseline risks. To the contrary, EPA's decision to use what it considers a "close enough" measure could have a significant impact on EPA's cleanup decision, because the risk described by EPA's RME is greater than the risk that needs to be remediated. For these reasons, accepting the new RME approach represented by EPA in the October 12 response would be inconsistent with the National Contingency Plan and EPA guidance, and is therefore arbitrary and capricious.

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[27] EPA October 12, 2012 Response at 22.

[28] RAGS, Vol. 1, Supplemental Guidance, Sec. 1.0, (Tab 29); see also 55 Fed. Reg. 8666, at 8710, (Tab 30) ("The reasonable maximum exposure scenario is 'reasonable' because it is a product of factors, such as concentration and exposure frequency and duration, that are an appropriate mix of values that reflect averages and 95th percentile distributions.")

These two fundamental problems manifest themselves in: (1) how to apply the exposure area; (2) the fish consumption rate for both recreational and subsistence fishers; and (3) whether to use whole body tissue in an RME scenario for the subsistence fisher pathway. Given the importance of this issue, the LWG disagrees with EPA that spending an additional 60 days to work out this "course correction" on RME is not warranted.

1. EPA's exposure area analysis is not reasonable because it does not appropriately consider the home ranges of all resident fish, does not evaluate the popularity of fishing locations, and does not relate consumption rates to the scale used.

EPA's October 12 response indicates it has misunderstood the LWG's position on the exposure area. The LWG did not state that fish consumption exposure should never be evaluated on spatial scales smaller than the defined site boundaries. In fact, the LWG has repeatedly indicated it is open to presenting evaluations of risk on smaller spatial scales (i.e., one river mile).[29] Rather, the LWG disagrees that an exposure area of one river mile should be used for the RME when combined with EPA's other exposure assumptions, such as the population exposed and the fish species consumed. As the LWG stated in its September 21 opening submission, even if a site-wide exposure is used for the RME, the BHHRA can still present smaller exposure areas to assess uncertainties.

As stated by EPA in the October 12 response, "exposures should be evaluated based both on the chemical distribution at the site, and the location and activity patterns of the potentially exposed populations." The first problem here is that using one-river mile is not relevant to the population exposed, nor is it directly tied to the chemical exposure of the fish consumed. The one river mile exposure area was established based entirely on the potential home range of smallmouth bass, not on the fishing patterns of the recreational or subsistence fishers. It is reasonable to assume that fishers would likely collect fish from locations throughout the site over the course of the assumed exposure duration of 30 years. But it is not reasonable to assume that individual fishers obtain all of the fish they ingest over 30 years from a single river mile. While there may be more popular fishing areas, there is no site-specific study or information available to identify them; selecting one-river mile as the exposure scale for the population would be completely arbitrary. In addition, given that EPA has changed course and assumes a multi-species diet, the one-river mile exposure scale has even less relevance, given that the other resident species contemplated for this scenario, which will be three-quarters of a person's multi-species diet, have home ranges larger than one-river mile.[30]

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[29] First, as stated in LWG's proposal submitted during informal negotiations, the RME could be designated based on smaller exposure scales if combined with a less conservative, mid-range fish consumption rate. EPA October 12, 2012 Response, Exhibit 16. Second, if the RME is based on a site-wide exposure using a higher end fish consumption rate, the BHHRA could present smaller scale evaluations (i.e. one river mile) for the recreational fisher to assess uncertainties. LWG September 21, 2012 Opening Submission, p. 21.

[30] The BHHRA presents carp, brown bullhead, and black crappie using fishing zones of three to four-mile segments based on the larger home ranges of these species. If a smaller scale is designated, an exposure area of at least three miles would be more appropriate given these species make up three-quarters of the multi-species resident diet.

These facts lead to the second problem: EPA is combining a very conservative assumption on exposure area with a higher-end consumption rate. Per RAGS A, the RME for a pathway is defined based on the combination of intake parameters.[31] It is not reasonable to combine a high-end fish consumption rate with an exposure point concentration representing a single river mile, especially when the fish consumption rate was intended to be applied to an entire water body. If the smaller exposure area is used for the RME, the fish consumption rate should be lowered to reflect the fraction of total fish intake that would be collected from the smaller fishing area.

2. EPA's failure to use the fish consumption rates that it acknowledges are correct is arbitrary and capricious, and EPA's reference to 200g per day consumption rates is inapplicable.

EPA relies on the Columbia Slough Study to support the application of 73 grams per day (g/day) as the consumption rate for the recreational fisher who eats fillet with skin. EPA makes this assumption despite the fact that EPA acknowledges that the appropriate fish consumption rate for fillet consumption based on the Columbia Slough study would be 29 g/day, not 73 g/day: *"Assuming fillet-only consumption and that 30 percent of the total weight of the fish is consumed, the corresponding rate is 29 g/day."* EPA dismisses the 29 g/day rate because the value is "...approximately within a factor of 2 of the 73 g/day value proposed by EPA. Thus, any revisions using a lower consumption rate than the 73 g/day as proposed would have minimal effect on the corresponding risk estimates for recreational fishers."[32] EPA provides no other justification for dismissing the consumption rate of 29 g/day, which by EPA's own admission more accurately reflects the data from the Columbia Slough study. EPA's declaration that "it's close enough" would create a risk assessment that is arbitrary and capricious and inconsistent with the NCP.

In addition, as noted in RAGS, the RME typically guides the evaluation of the protectiveness of remedial alternatives and the establishment of cleanup goals.[33] A factor of two does have a significant effect in calculating preliminary remedial goals for the site, and would become a significant consideration in the selection of final cleanup goals. By agreeing that 29

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[31] RAGS A, Section 6.4.1, p. 6-19 (Tab 29): "For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway."

[32] EPA October 12, 2012 Response, p. 14.

[33] RAGS A, Section 6.4.1, p. 6-5 (Tab 29) ("Actions at Superfund sites should be based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future land-use conditions." (emphasis omitted)). *See also* Preamble to the NCP, 55 FR 8710 ("EPA is clarifying its policy of making exposure assumptions that result in an overall exposure estimate that is conservative but within a realistic range of exposure. Under this policy, EPA defines 'reasonable maximum' such that only potential exposures that are likely to occur will be included in the assessment of exposures. The Superfund program has always designed its remedies to be protective of all individuals and environmental receptors that may be exposed at a site; consequently, EPA believes that it is important to include all reasonably expected exposures in its risk assessments."); An Examination of EPA Risk Assessment Principles and Practices, Section 5.1.2, p. 102 ("Pursuant to the NCP, decisions at Superfund sites are based on cancer risks and non-cancer health hazards associated with RME estimates under both current and future land use conditions."); *id.* at Section 5.6, p. 119 ("For the Superfund program, EPA bases decisions on current and future risks associated with reasonable high-end exposures or RME, not only the average exposures.").

g/day is in fact the correct rate to use from the Columbia Slough study, but then refusing to use it in the risk assessment, EPA is establishing a basis for potentially responsible parties to challenge EPA's cleanup plan. This is not good for the LWG, EPA, or the community.

EPA's reference to the consumption rate of 200 g/day is not relevant for the discussion of recreational fish consumption rates.[34] First, 17.5 g/day is the 90th percentile for consumers and non-consumers and the 200 g/day rate is the 90th percentile for consumers only. These percentiles are from a national dietary study on fish-containing foods in general for the entire U.S. population and do not correlate to fish consumption by recreational fishers. Furthermore, the national dietary study is a two-day dietary recall study where the consumer versus non-consumer designation is determined based entirely on whether fish-containing food was consumed during that two-day period.

The reason EPA and LWG agreed to use the 17.5 g/day in the BHHRA and the reason the LWG recommended using it for Portland Harbor to represent the recreational fisher is because EPA's Ambient Water Quality Guidelines recommend the use of 17.5 g/day as the default fish consumption rate for recreational fishers in the absence of site-specific studies.[35] Per EPA's Ambient Water Quality Guidelines, EPA believes that 17.5 g/day is representative of fish intake for sports fishers and should be used in the absence of applicable consumption rates from local, State, or regional studies. According to the standards that EPA established for conducting and using fish consumption surveys at the site,[36] there are no consumption rates available from local, State, or regional studies that are appropriate for use in the risk assessment. Given that 17.5 g/day is the value recommended by EPA for recreational fishers in the Ambient Water Quality Guidelines, there is no basis for using a different data set from the national dietary study to argue for an alternative value for recreational fish consumption.

Finally, EPA misrepresents the issue associated with migratory fish consumption, which has an impact on the fish consumption rate selected for the RME. It is true that an evaluation of risks associated with consumption of migratory fish is not informative about risks from contamination in Portland Harbor. That is why the Portland Harbor risk analysis uses resident fish tissue data. However, recreational fishers are likely to consume both resident and migratory fish species.[37] Therefore, evaluating risk from only resident fish justifies the use of a lower fish consumption rate because it represents only part of the total fish consumption, as the overall fish

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[34] Table 6 provides the LWG's response to several other fish consumption studies cited in EPA's October 12, 2012 Response, p. 15, that are not further discussed in this reply.

[35] EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), Section 4.3.3.1, p. 4-24 (Tab 42): "EPA recommends default fish intake rates for recreational and subsistence fishers of 17.5 grams/day and 142.4 grams/day, respectively."

[36] EPA comments on the Programmatic Work Plan (July 25, 2003), p. 53 (Tab 35): "a well done fish consumption study that provides usable quantitative data, whether for the risk characterization or for comparison with existing studies, would require at least two to three years to complete and cost several hundred thousand dollars"

[37] DEQ Portland Harbor RI/FS Work Plan (draft, March 31, 2000), Section 9.2.4, p. 200 (Tab 49): "In contrast, recreational fishing is extremely popular throughout the lower Willamette basin. Resident species such as largemouth bass, black crappie, white crappie, and walleye support a significant year-round recreational fishery. Species most desired by most recreational sport anglers are spring chinook, steelhead, coho, shad, and white sturgeon."

consumption would include both resident and migratory fish. Instead, it appears that EPA wants to take fish consumption rates that are based on all fish—migratory and resident species—and apply it only to resident fish consumed from Portland Harbor without any adjustment factor. This is particularly troubling with respect to the 142 g/day subsistence fisher given the use of the high consumption rate. When EPA combines a high rate – 73 g/day recreational or 142 g/day subsistence – with the other conservative assumptions (e.g. one-river mile exposure area or whole fish) it creates an RME scenario that is highly unlikely to occur.

3. Whole body consumption is not a likely scenario and should only be part of an uncertainty analysis, not an RME.

The LWG disagrees with EPA's use of whole body consumption for the subsistence fisher RME. As EPA acknowledges, consumption of the entire fish may not represent a common practice.[38] Therefore, whole body fish consumption is not a reasonable assumption for use in the RME (again, according to guidance an RME scenario is not to represent the worst-case, but the upper bound of a likely and recurring exposure). Subsistence fishers may consume portions of the fish other than the fillet tissue, but the consumption of other portions of the fish would be at lower rates than that assumed for fillet tissue. Therefore, it is not appropriate to combine an upper percentile consumption rate with whole body tissue for the RME scenario. In addition, the RME includes other assumptions that offset not considering the potential consumption of other portions of the fish, such as the assumption of no reductions from preparation or cooking methods.

4. The RMEs have evolved through the dispute process and a short additional time period to finalize the RME scenarios is appropriate.

Although the inclusion of RMEs is contrary to is prior agreements with EPA, the LWG does not dispute EPA's determination to include RMEs for a recreational fisher and a high consumption (subsistence) fisher. However, EPA and LWG should take the time to get the RME scenario right. The RME guides selection of cleanup goals and could have significant impacts to EPA's cleanup decision, in terms of protectiveness and costs. Given that the range of cleanup costs estimated in the draft feasibility study is between $200 million and $1.8 billion, it is prudent to consider the issue carefully.

EPA claims that the fish ingestion rates have been a subject of deliberation with LWG for the past 10 years. That simply is not true. While there was significant debate on those issues during the two years prior to the approval of the Programmatic Work Plan in 2004, there has been no significant discussion of the fish consumption approach since. The prior agreements on the scenarios and the context of their use have informed decisions and activities at the site until now. EPA's change in approach at this late stage in the process (i.e., the second draft of the BHHRA) should be carefully deliberated to ensure that the RME is based on an appropriate mix

[38] EPA October 12, 2012 Response, p.13 ("EPA acknowledges that consumption of the entire fish may not represent a common practice, but that the degree to which whole body data may overestimate intake should be assessed as an uncertainty.").

of mid- to high-end range exposure factors and includes consideration of how the available data will be used.[39]

The LWG requested the 60 day period to finalize the RMEs because EPA verbally presented the concept of its new proposal on RME only in the last 15 minutes of the last informal dispute meeting on September 10, 2012. At that meeting, EPA stated that the staff had not discussed the proposal even amongst themselves yet and it was still being developed. EPA then followed up with the complete proposal in the email dated September 11, 2012. The LWG responded by asking for time to discuss the details because the LWG believed a reasonable resolution could be reached that is technically and legally sound. EPA denied this request. While delay is certainly a concern of the LWG, we do not believe that two months of discussion will delay the overall RI/FS schedule given that LWG is still waiting for EPA's comments on the second draft Remedial Investigation report, which EPA has had for 14 months, and waiting for EPA's feedback on the draft Feasibility Study, which EPA has had for 7 months.

B. The addition of explanatory language to the BHHRA is necessary to provide an adequate description of the actual risks relating to exposure though domestic drinking water use and clam consumption.

Table 5 to the LWG September 21opening submission shows exactly what is at issue here. The LWG is asking EPA *to add just 36 words* to its explanation of the domestic drinking water supply and clam consumption scenarios that are evaluated in the risk assessment – 16 words with respect to drinking water and 20 with respect to clam consumption. EPA is correct that it has now agreed to include all these words in the "Uncertainty Analysis" section, which currently begins at page 100 of the BHHRA.[40] The LWG believes that the explanation these words provide needs to be included in the Exposure Assessment section as well. You should require this change because it is consistent with EPA guidance as explained in the LWG's September 21 opening submission, because it is consistent with the practice of other EPA regions, and because it is the most forthright way to explain this part of the risk assessment to the public.

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[39] For example, the focus is moving from single species to multi-species consumption. EPA wants to use a one river mile exposure scenario, but only bass data are available for one river mile segments because these are the only species where the one-river mile scenario is relevant. EPA and LWG should carefully determine how concerns about smaller exposure scales can be evaluated given the data set available and the home ranges of all four species. EPA suggests substituting bass data for the three other species; that approach does not allow evaluation of a multi-species diet as it would result in an RME that is based on one river mile using a single species diet of bass. The other three fish species (carp, brown bullhead, black crappie) were collected over fishing zones representative of those species' home ranges (three to four miles), and those data could be used to evaluate multi-species diets on a smaller exposure scale, if needed.

[40] EPA states in its October 12 response at page 16 that its June 2012 directed redline of the risk assessment did not delete this language but retained it in the uncertainty section. This is incorrect. EPA originally deleted this information entirely. Over the course of negotiations since June 2012, it has agreed to add it back, but only to the Uncertainty Analysis section. *See* Exhibit 1 to LWG Opening Submission at pages 108 and 109.

1. Domestic drinking water supply

To understand why this is important in the context of drinking water, it helps to start at the end. The risk assessment reaches two conclusions with respect to drinking water. First, if someone is a transient who drinks surface water directly from the river and uses it for bathing, assuming up to two years of continuous exposure, he or she faces no unacceptable risk.[41] However, *if* someone *were to use untreated* surface water as a *permanent domestic water source in his or her house 365 days a year for up to 30 years*, then that person faces unacceptable risk from PAHs (and from MCPP if the water is drawn solely from two specific areas of the river). EPA and the LWG agree that there is no current domestic water supply use and that the City of Portland does not anticipate any such future use. The LWG and EPA's professional risk assessors are also clear in their understanding of the assumptions that are used in the domestic drinking water scenario that is nonetheless evaluated in the BHHRA—this scenario assumes that someone installs a pipe and pump system to deliver untreated surface water from the Willamette River in the Portland Harbor directly into his or her house without any conventional water treatment and then uses it for 100 percent of his or her drinking, cooking and bathing needs for a period of up to 30 years.[42]

You need to answer two questions. Given how EPA proposes describing this scenario, primarily in the Uncertainty Analysis section, will the assumptions that have been used be clear to the public? And, more importantly, does the public deserve to have the important contextual information from which to understand the likelihood of that scenario occurring, and therefore the relative weight that should be applied to it in risk management decisions, up front in the document, rather than be required to dig into the Uncertainty Analysis to discover it? The LWG believes the answer to the first question is "no," and the answer to the second question is "yes," and that both concerns can be addressed with the addition of a few words.

Making this change will be consistent with the approach to providing context information relied upon by EPA in the risk assessment prepared by the Wisconsin Department of Natural Resources (WDNR) for the Lower Fox River. Within the first seven pages of the BHHRA section of that document, WDNR explained fully the drinking water uses of the different segments of the Lower Fox River. For example:

> "From Lake Winnebago to the dam at Appleton, the Lower Fox River serves as a secondary source of drinking water for the communities of Neenah, Menasha, and Appleton. *All river water is treated prior to joining the water-distribution systems in these communities.*"[43]

In the Lower Fox, there was even more reason to evaluate the domestic water supply scenario in the first place. Although the Lower Fox River is not used as a primary drinking

[41] *See* Section 5.2.3 of the September 17, 2012 EPA/LWG redline of the BHHRA.
[42] *See* May 2011 Draft Final BHHRA, Table 3-30 (Tab 15).
[43] Wisconsin Department of Natural Resources, Final BHHRA and Ecological Risk Assessment for Lower Fox River and Green Bay, Wisconsin at Tab 44 of LWG Opening Submission, p. 5-7 (2002).

water source, it is used as a secondary source by some communities. [44] In Portland Harbor, the Willamette River is not used currently by anyone as a primary or secondary drinking water source, and there is no currently anticipated future use. The only reason the domestic water supply scenario is being evaluated is because Oregon's designated beneficial use of the Main Stem Willamette River includes designations for Public Domestic Water Supply and Private Domestic Water Supply. However, both of those designations are clearly described as being "with adequate pretreatment and natural quality that meets drinking water standards." All that the LWG is asking is that, parallel to the explanation provided in the quote above from the risk assessment for the Lower Fox, the explanation of the scenario in Portland Harbor explain that the designated beneficial use assumes conventional pretreatment.[45]

2. Clam Consumption

At issue here is whether the BHHRA should explain up front in the risk assessment two undisputed facts: (1) that the only clams that have been found in the Portland Harbor are an invasive, non-native species, and (2) that Oregon law prohibits harvesting them.

EPA does not address at all in its October 12 response why, while it states in section 3.3.6 of the risk assessment that the only clams found in the Study Area were Asian clams (*Corbicula* sp.), it is not willing to add the explanation "which are an invasive, non-native species." This is undisputed factual information that should be included for the public's benefit, and it will be confusing to the public without it (i.e. otherwise what is the public to infer from the information that they are Asian clams?). You should decide that this language be included.

On the second point, EPA argues that the fact that Oregon law prohibits harvesting this invasive, non-native species should be not included because that is an "institutional control," and baseline risk assessments should not assume application of any institutional controls. EPA argues that there is no relevant definition of "institutional control" to guide this determination.

You don't need a formal definition of "institutional controls" to resolve this. You need only look at what the baseline risk assessment is supposed to do:

> "The role of the baseline risk assessment is to address the risk associated with a site in the absence of any remedial action or control, including institutional

[44] As EPA notes in its October 12 response, LWG's Opening Submission incorrectly states that the Lower Fox River excludes the drinking water scenario entirely. However, the LWG is not requesting that you go so far as to exclude the drinking water scenario from the BHHRA. It is only asking that the Portland Harbor BHHRA follow the precedent of the Lower Fox BHHRA by including the information that Oregon's designation of the Willamette River for public or private drinking water supplies includes an assumption of conventional pretreatment.

[45] Contrary to footnote 17 of EPA's October 12 response, the LWG is not suggesting it should be assumed that there will be any special treatment for hazardous substances. However, pretreatment for just conventional parameters (like removal of solids) impacts water quality substantially. ODEQ has interpreted the drinking water beneficial use designation to require surface waters to "be of sufficiently quality that it is possible for them to meet drinking water standards with conventional treatment measures." IDEQ/ODEQ, Snake River – Hells Canyon TMDL, p. 71 (rev. June 2004) (Tab 39).

> controls. The baseline assessment is essentially an evaluation of the no-action alternative."[46]

Therefore, in order to decide what information is important to include in the baseline risk assessment, you should ask whether the BHHRA is adequately describing what the baseline, no-action conditions are in Portland Harbor. Part of that no-action baseline condition is the fact that Oregon has a law that has nothing to do with Portland Harbor or even with contamination, which prohibits the harvesting of non-native wildlife, including these Asian clams. That law is in place now, and it will remain in place whether or not there is any action in Portland Harbor. It is therefore part of the baseline, no action, condition, which the preamble to the NCP says should be described in the risk assessment.[47]

This law is not a "remedial action or control including institutional controls." However, even if EPA thinks otherwise, the LWG does not understand EPA's objection to including this information in the exposure assessment section given that EPA has agreed to include it in the uncertainty analysis section of the BHHRA. EPA's argument that relevant Oregon laws are institutional controls that should not be included in a baseline risk assessment does not justify excluding them from the exposure assessment section while including them in another section of the BHHRA.

Accordingly, the 20 word explanation that the LWG has proposed should be included in section 3.3.6. As described in the LWG's Opening Submission, this is consistent with the treatment of a very similar issue by EPA Region 1 for the Housatonic.[48]

C. The LWG believes the BHHRA should include a concise statement of the major conclusions of risk assessment.

We are pleased that EPA agrees that the BHHRA should include an executive summary and a table of contents. We continue to believe that a concise statement of the major conclusions of the risk assessment would be helpful to non-technical readers of the document. The Baseline Human Health Risk Assessment for the Lower Duwamish Waterway, for example, includes a brief, plain-English identification of the contaminants that present the majority of the risk at the

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[46] 55 Fed. Reg. 8,665, 8,710-11 (1990) (Tab 30).

[47] "EPA agrees that risk assessments conducted for the Superfund should take into consideration background concentrations and *conditions and should identify these critical assumptions and uncertainties in its risk assessment.*" 55 Fed. Reg. 8,665, 8,710 (1990) (Tab 30).

[48] "A construction worker scenario was not considered a complete exposure pathway because flooding and wetland protection regulations preclude major construction in the floodplain. Therefore, the construction worker scenario was not evaluated further in the risk assessment." ACOE/EPA, HHRA, GE/Housatonic River Site, Rest of River, Vol. I, p. 7-8 (Feb. 2005) (Tab 46).

site, and where those chemicals occur. We agree with EPA's view that "it is imperative that the document be clear as possible regarding the major assumptions and conclusions." [49]

D. EPA should adopt the September 17, 2012 version of the BHHRA and Tables 1 and 2.

The LWG has disputed EPA's June 2012 directed redline of the BHHRA. We believe it is critical that all matters necessary to finalize the BHHRA be resolved by this dispute. EPA concedes that Tables 1 and 2 to the LWG's September 21 opening submission "generally reflect" the agreed resolution of issued raised by the LWG concerning the June 2012 directed redline. We request that you adopt these Tables as revisions and corrections that will be made in the final BHHRA.

III. The LWG is asking for meaningful coordination, not an amendment to the Consent Order.

We want to be clear: The LWG is not seeking to amend the Consent Order through dispute resolution or to dilute EPA's enforcement authority. We have simply requested a meeting between the ECL Director and LWG senior management to establish agreed upon protocols consistent with the Consent Order to guide a better working relationship between EPA and the LWG. We think that the Consent Order already provides all of the necessary tools to support the open communication, trust, and flexibility that are essential to effective collaboration.

First, the Consent Order requires EPA to meet with the LWG in an effort to avoid disputes.[50] This requirement was added to EPA's first draft of the Consent Order at the LWG's request,[51] because EPA and the LWG agreed that open communication was critical to the success of the Portland Harbor RI/FS. EPA's concern that a commitment to better communication might deviate from the model consent order should not be an issue.

Second, the Consent Order identified a Project Coordinator with "the authority lawfully vested in a Remedial Project Manager (RPM) and On-Scene Coordinator (OSC) by the NCP."[52] The National Contingency Plan provides the RPM with authority to "coordinate, direct and review the work of ... responsible parties to assure compliance with the ... consent order."[53] The Portland Harbor RI/FS has been a complicated, iterative investigation; as of September 2012, the LWG was still awaiting EPA approval of nearly 70 deliverables going back to 2004. The LWG has been willing to press on, because we have trusted in the RPMs' authority to make day-to-day decisions about each next step of the investigation. Only after we received EPA's June 22, 2012 directed redline were we advised of Region 10's opinion that only the ECL Director can make such decisions. We learned only in the October 12 response that it is "wholly unreasonable" for us to understand the term "comprehensive set of comments" to mean all of

[49] EPA October 12, 2012 Response, p. 3.
[50] Consent Order, §IX.1.
[51] Dost email to E McKenna, February 28, 2001 (Tab 51).
[52] Consent Order, §XV.4.
[53] 40 C.F.R. §300.120(f)(2)

EPA's comments that must be resolved to finalize a document.[54] We also learned that although EPA had gone to considerable lengths in the past to distinguish directive comments from non-directive ones, those were meaningless distinctions without a difference, because EPA intended to enforce all equally. As we have said repeatedly, we understand that EPA needs flexibility to respond to changed circumstances, and that a decision that makes sense the day that it is made can result in unintended consequences that may require revisiting. But we think the RPMs are already authorized by the Consent Order and the NCP to make reliable decisions about the Portland Harbor and to communicate with the LWG when an adjustment appears necessary.

Finally, the Consent Order includes a dispute resolution provision that was expressly modified from the model order ("any disputes may be resolved"[55]) to allow the parties broad flexibility to solve problems as they arise. As Charlie Ordine put it during our negotiation of the Consent Order, the dispute resolution provision was hardly worth discussing, "since your clients will undoubtedly be able to elevate any dispute to our regional administrator & politicians beyond whenever they see fit."[56] Therefore, in the same way the Consent Order by its terms allows us to use the dispute resolution provision as a means to address EPA's failure to honor its agreements with the LWG without notice or explanation (a "dispute[] concerning activities ... under this Order"), the Consent Order does not limit our options for solving problems that arise during the RI/FS.

This approach is entirely consistent with EPA guidance, which encourages EPA to "engage in open dialogues" with parties performing under EPA settlement agreements:

> "Successful working relationships depend on regular, clear and open communications between parties, shared commitment to reaching common goals, mutual understanding of expectations, flexibility to changing conditions, and a willingness to listen."[57]

A commitment to communication and shared expectations between EPA and PRPs is not "problematic under the CERCLA statutory scheme"[58] as EPA's October 12 response suggests; it is EPA's express policy.

We disagree with EPA's view that it was "under no requirement to notify the Respondents prior to modifying the BHHRA, nor was EPA required to discuss the basis for our modifications prior to providing them the modified BHHRA."[59] But our real question is, obligated or not, why didn't EPA talk to us about the BHHRA when it decided that a "correction in course" was necessary? Whether EPA has the legal authority to unilaterally walk away from years of detailed, negotiated agreements without

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[54] EPA October 12, 2012 Response, fn. 4.
[55] Consent Order, §XVIII.1 (emphasis added).
[56] Ordine email to Newlands, July 27, 2001, attached at Tab 54.
[57] Interim Guidance on Implementing the Superfund Administrative Reform on PRP Oversight (EPA, May 17, 2000), p. 3.
[58] EPA October 12, 2012 Response, p. 23.
[59] EPA October 12, 2012 Response, p. 22.

a word of explanation is an entirely different question than whether EPA ought to interact with cooperative, competent settling parties in this manner.

The Portland Harbor Superfund Site has a long way to go. EPA and the LWG still have to finalize the ecological risk assessment, the remedial investigation, and the feasibility study. Once EPA makes decisions about the remedy, EPA will expect someone to do the remedial design and conduct the remedial action. The success of all of this depends on cooperation between EPA and responsible parties. We are extremely concerned that the collapse of the working relationship between EPA and the LWG brought on by EPA's directed revisions to the agreed content of the draft final BHHRA along with enforcement action will not only impair the timely finalizing of the RI/FS documents but also EPA's ability to build a much larger coalition of performing and funding parties that will be necessary to implement the Portland Harbor remedy. EPA staff's view that the process is not "broken" but "actually worked as the AOC was designed" is simply wrong. If they truly believe that, then a "correction in the course" in the parties' working relationship – not just in the BHHRA – is essential.

For these reasons, we respectfully request that you agree to schedule a meeting between the ECL Director and LWG senior management to develop a process, within the framework of the existing Consent Order and current EPA policy and guidance that not only restores trust and confidence between EPA and the LWG, but inspires trust and confidence in the other responsible parties who will ultimately be asked to participate in the Portland Harbor cleanup.

Conclusion

For all of the reasons stated above, we ask you to:

1. Withdraw the June 22, 2012 notice of noncompliance with the Consent Order and the June 29, 2012 threat to issue stipulated penalties;

2. Retract EPA's June 2012 directions on the RME case for fish consumption, do not adopt EPA's October proposal, and direct staff to work with the LWG for a 60-day period on development of an RME case that is consistent with guidance, as outlined above;

3. Direct EPA staff to insert relevant factual information into the exposure assessment and risk characterization sections of the BHHRA regarding the drinking water scenario and clam consumption scenario;

4. Direct EPA to include a conclusion section to the BHHRA in addition to the table of contents and executive summary;

5. Approve the agreed revisions reflected in Exhibit 1 and Tables 1 and 2 to be incorporated into the BHHRA; and

6. Commit to meet with the LWG Senior Management and to establish a mutually-agreed upon set of documented protocols to guide a better working relationship between the

LWG and EPA such that EPA can successfully manage the RI/FS through to completion and facilitate a solid partnership with the responsible parties to clean up Portland Harbor.

The LWG looks forward to moving beyond this dispute toward finalization of the RI/FS and the identification of protective remedies that can be implemented at Portland Harbor.

Sincerely,

The Lower Willamette Group

cc: Lori Cora
Kristine Koch
Chip Humphrey
Elizabeth Allen

Enclosures:
Table 5: LWG Proposed BHHRA Revisions re: Exposure Scenario Context Information
Table 6: LWG Response to Fish Consumption Studies Cited by EPA
Additional reference material on CD, Tabs 50-54

EXHIBIT 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF
WATER AND WATERSHEDS

December 6, 2012

MEMORANDUM

SUBJECT: Formal Dispute on the EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment (BHHRA) and Request for Dispute Resolution; Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 – **Final Resolution**

FROM: Daniel D. Opalski, Director
Office of Water & Watersheds

TO: File

By addressing explicitly the first and second "Issues for Resolution" identified by the Lower Willamette Group in its September 21, 2012 "Opening Submission" and incorporating by reference the Partial Resolution of October 25, 2012, this memorandum serves as the Final Resolution of the above-referenced dispute under the Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 (hereafter "Order on Consent").

A. The first issue, as summarized on page 5 of the "Opening Submission," is as follows:

> "The May 2011 draft final BHHRA was consistent with agreed resolutions of EPA comments and did not violate the Consent Order."

In expanding upon this assertion, the Lower Willamette Group presents a number of arguments, including the following: 1) that the May 2011 BHHRA is, in fact, consistent with agreed resolutions of prior EPA comments; 2) that EPA inappropriately considered both "directed" and "non-directed" comments when evaluating whether the Lower Willamette Group was in compliance with the Order on Consent; and 3) that to the extent EPA's determinations identified deficiencies, the number and/or type of issues identified by EPA as the basis for a determination of noncompliance are "trivial" individually and together in comparison to the overall effort. The Lower Willamette Group urges that these arguments together lead to the conclusion that EPA's finding of noncompliance with respect to the BHHRA was in error. Below, I evaluate each of these assertions in detail.

1) Consistency with Agreed Resolutions

As an initial matter, I have reviewed, in particular, EPA's Exhibit 6, the Lower Willamette Group's "Opening Submission," and pages 7 and 8 of the Lower Willamette Group's October 24, 2012 "Reply." I find sufficient ambiguity in EPA's direction and/or the adequacy of the Lower Willamette Group's

Formal Dispute on the EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution; Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, USEPA Docket No. CERCLA-10-2001-0240 – **Final Resolution**

Administrative Record Summary

1. Lower Willamette Group Opening Submission – Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and request for Dispute Resolution, Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket no: CERCLA-10-2001-0240, including Exhibit 1, Tables 1 -5, and Supporting Documentation CD, September 21, 2012
2. EPA Response to Lower Willamette Group Opening Submission, including Supporting Documentation CD, October 12, 2012
3. Lower Willamette Group Reply to EPA Submission, Formal Dispute on EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution, including Tables 5 and 6 and Supporting Documentation CD, October 24, 2012
4. Oral presentations and discussion among the parties, November 1, 2012
5. Lower Willamette Group Response to Follow-up Request for Information, November 13, 2012
6. EPA Response to Dan Opalski's November 6 Questions (Email transmittal from Lori Cora via Chip Humphrey), with attached "2012-11-09 EPA Assessment of Respondents Tables 1 & 2" and "List of Tasks to complete BHHRA 11-07-2012," November 13, 2012

addressing of the comment to warrant withdrawing Items 1, 12, and 17 from Exhibit 6 as part of EPA's basis for its determination of noncompliance. Specifically, with respect to Item 1, I find that the back and forth communications subsequent to EPA's initial comments appeared to muddle rather than clarify what EPA expected of the Lower Willamette Group for an adequate incorporation of the comment. Regarding Item 12, although the Lower Willamette Group's approach to addressing the comment seemed to miss the mark, in its rewrite EPA did not do a demonstrably better job addressing its own comment and, unlike in the case of several other comments, did not make compensating adjustments elsewhere in the text. This has the effect of calling into question the intent of the original comment. Finally, had EPA provided clear, blanket direction to delete/modify any language similar to "same rate every day of every year for 70 years" as referred to in Item 17, it would have been appropriate to hold the Lower Willamette Group to finding and modifying each instance of such language. It was not unreasonable to expect the Lower Willamette Group to be more thorough in identifying similar language without the need for such blanket direction, but I believe that EPA's failure to state explicitly its expectation warrants the removal of Item 17 from Exhibit 6.

Having removed these three Items (and Item 11, which was withdrawn previously by EPA), however, I find that EPA otherwise has carried its burden of demonstrating deficiencies by the Lower Willamette Group in addressing thirteen prior EPA comments. I make this finding based on my review of the original EPA comments, the language of the May 2, 2012 version of the BHHRA, and representations of the parties' intervening communication about the comments.

2) Directed Versus Non-directed Comments

The Lower Willamette Group argues for a distinction in the significance of "directed" and "non-directed" comments, an argument of potentially greater significance because only one "directed comment" remains as part of the basis for a noncompliance determination. From my review of the comments identified in EPA's Exhibit 6, it is clear that despite how the comments may be labeled, each of the non-directed comments includes directive language that cannot reasonably be read other than to create an expectation that Respondents make a change or modification to address the comment.[1] It seems entirely appropriate and most accurate; therefore, to consider these comments part of "EPA's directions for changes," consistent with the language in Section IX, Paragraph 4 of the Order on Consent, which the Lower Willamette Group argues sets a different enforcement bar. Further, in the Lower Willamette Group's Tab 12, in this instance EPA explicitly communicated that resolving its comments would be achieved by "...addressing all directed and non-directed comments consistent with previous directions and agreements..." This language is unambiguous; it sets forward EPA's expectation that all comments be addressed. This tracks the requirement of Section IX, Paragraph 1 of the Order on Consent: "At EPA's discretion, Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables within a time frame specified by EPA."

[1] I note that in some cases the non-directed comments are less specific in identifying the changes to be made, but they are nonetheless sufficiently clear in identifying the issue or issues that need to be addressed. In these instances, the quality of a revision turns not on direction regarding specific language, per se, but on whether the issue identified is addressed adequately in the revised language chosen by the Respondents. As a corollary, the nature of "agreed resolutions" of comments that don't direct specific language modifications can also be non-specific, i.e. the commitment is to make changes consistent with the comment without indication of the wording that will be used to meet this commitment. Under this circumstance, assessment of adequacy of a change or resolution has to track back to the initial comment, not the apparent "agreed resolution."

The Lower Willamette Group also cites EPA's practice on the project of delineating between directed and non-directed comments when providing input to the Lower Willamette Group. It is plausible that this approach could have led to a belief that non-directed comments would be considered differently in an enforcement context. However, the Order on Consent does not make this distinction, as EPA points out in its "Response." Nor has the Lower Willamette Group presented any evidence that EPA ever relinquished its rights or remedies under the Order on Consent with respect to the addressing of EPA comments. That EPA has not previously made a finding of noncompliance based on non-directed comments does not bind how the agency may proceed under the Order on Consent. The Lower Willamette Group's perception that EPA has fundamentally changed its approach with this action without appropriate communication has been raised energetically by them, and consistent with the Partial Resolution, further communication on this issue between the parties is warranted. This does not, however, change the basic legal analysis of EPA's discretion to proceed under the Order on Consent.

I believe the Lower Willamette Group has over-read the significance of the distinction between directed and non-directed comments. To the extent a non-directed comment clearly communicates a need for a modification and provides sufficient clarity on what that modification needs to address – as is the case with the comments provided in Exhibit 6 – I find that that Respondents' treatment of both directed and non-directed comments can provide the basis for an EPA determination of Respondents' noncompliance with the Order on Consent.

3) Significance of the Number and Type of Deficiencies

Although the Lower Willamette Group does not agree with EPA's determination of noncompliance, the Lower Willamette Group (essentially) emphasizes that even if EPA believed there were some deficiencies, it was more appropriate in this case for EPA to exercise its enforcement discretion by withdrawing the noncompliance determination. The Lower Willamette Group highlights that in its basis for a determination of noncompliance, EPA identified continued concern with how only 16 of its original 223 comments were addressed in the May 2, 2012 BHHRA. They also state that even for the majority of these 16 comments, EPA's own redraft of the BHHRA does not adopt the revision EPA called for, suggesting relative unimportance of the comments.

In response to a question during oral presentations pursuant to this dispute, the Lower Willamette Group asserted that a finding of noncompliance by EPA should be reserved for when there are egregious deficiencies, restating a position they put forth in their written submissions. This proposed compliance gradation is neither particularly objective nor, more importantly, present in the Order on Consent. As a matter of the numbers, after EPA's withdrawal of Item 11, the comments identified as the basis for EPA's determination of noncompliance represent just over seven percent of the total number of original comments. With further reductions of the list as provided herein, this figure is now less than six percent. This represents substantial progress, as recognized by EPA. On the other hand, the BHHRA has been in the works for a number of years, and during that period there have been numerous oral discussions and written exchanges between the parties regarding comments and issues. In fact, many elements of the BHHRA have been in active discussion from the earliest days of the remedial investigation/feasibility study process at the site, long before the drafting of the BHHRA. So it is reasonable for EPA to expect a very high level of resolution at this point in the process. Part of the rationale for an "all comments addressed" standard is that in any particular instance, the significance of potential deficiencies may be

much less about the number of those deficiencies and much more about the substance to which those deficiencies relate. In this context, though EPA unquestionably has some discretion, EPA's "Response" is correct in asserting that even a single comment being addressed inadequately can be the basis for a determination of noncompliance.

I do not disagree with the Lower Willamette Group's contention that the part of EPA's exercise of its discretion can include consideration of the significance of the substance of a given deficiency/comment. On this point, the Lower Willamette Group alleges that EPA's decision not to incorporate its own previous direction into its June 22, 2012, draft of the BHHRA gave a clear indication of the insignificance of the comments in question. EPA argued that in its substantial rewriting of the BHHRA, it had in several cases made changes in the wording and/or organization of the document that effectively satisfied the original comment without following through with the revision initially envisioned. In other cases, where EPA's initial comments asked for a rationale or explanation to justify certain language included in the draft BHHRA, EPA decided to drop the language altogether rather than struggling to come up with a justification for Lower Willamette Group language EPA was questioning in the first place. These two approaches suggest not that the deficiencies were insignificant, but that there were multiple approaches to resolving them. But more generally, the Lower Willamette Group seems to argue that the comments were not significant enough to provide the basis for a noncompliance determination. However, taken as a whole, nearly all of the deficiencies pointed to a tendency in the original draft toward language that downplays risk or overemphasizes the conservativeness of the risk assessment, a subject about which EPA has provided feedback at both the staff and management levels for several years. This is an area of substantial importance in the assessment, characterization and communication of risks posed by the site. On these bases, I do not find compelling the Lower Willamette Group's argument that EPA's comments lack significance or substance.

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In conclusion, therefore, I affirm that the May 2, 2012, BHHRA failed to address EPA comments, and that this failure was sufficient to justify a finding of noncompliance with the Order on Consent. I do not find sufficient reasons to justify overturning EPA's determination of noncompliance as a matter of enforcement discretion. I leave it to the Director and Associate Director of the Office of Environmental Cleanup to consider as they deem appropriate the discretion available in Section XIX of the Order on Consent with respect to imposition of stipulated penalties.

B. The second issue, as summarized on page 10 of the "Opening Submission," is as follows:

> "Certain of EPA's directed revisions to the May 2011 BHHRA are inconsistent with EPA Guidance."

With respect to this issue, I have the benefit of the progress made by the parties in prior stages of the dispute. As an initial matter, the parties both request that the September 17, 2012, revision of the BHHRA should be adopted, with any changes resulting from this decision to be made to this version to create the final BHHRA. The Lower Willamette Group goes further in requesting adoption of its issue resolution tables (Tables 1 and 2), but there is no agreement between the parties on the specific information in these tables. Regarding Tables 1 and 2, I agree with EPA that the adoption of the Tables

along with the September 17, 2012, version of the BHHRA would be inconsistent given that the Tables were not updated to reflect the latest status of the document. Therefore, I am directing adoption of the September 17, 2012, version of the BHHRA, but not of Tables 1 and 2. What then remains of this dispute are three relatively specific issues, the resolution of which should frame the path to the final BHHRA. I will take these up in the order of their presentation in the Lower Willamette Group's "Opening Submission."

1) "EPA's direction on what constitutes a reasonable maximum exposure is inconsistent with guidance, inconsistent with national policy, and arbitrary and capricious."

The fish consumption exposure scenarios are at the heart of the Lower Willamette Group's contention that EPA's revisions to the May 2011 version of the BHHRA were inconsistent with guidance. Although the Lower Willamette Group takes issue with specific aspects of the scenarios, their fundamental contention is that, by its selection of combinations of key exposure factors, EPA defined reasonable maximum exposure (RME) scenarios that cannot be reasonably expected to occur in the context of the Portland Harbor site. Both parties make fair arguments regarding choices for the key exposure factors, but the uncertainties—acknowledged by both parties but given different weight or merit by them—make it difficult to land too definitively on one answer. Indeed, as correctly pointed out by the Lower Willamette Group, EPA's regulations and guidance do not prescribe a specific RME, but rather provide that the RME must fit within the range of plausible exposures, albeit as a more "conservative" case within this range to insure protectiveness. In this context, the Lower Willamette Group has not provided a convincing case that EPA's RME scenarios are inconsistent with guidance. Regardless, as described in detail below, this final resolution establishes revised RME scenarios that are consistent with EPA regulation, guidance, and national policy.

I also note that the written submissions and the oral presentations in this dispute provide adequate basis for me to conclude that direction regarding the RME scenarios was not arbitrary and capricious, as alleged by the Lower Willamette Group. I have addressed the alleged inconsistency with guidance, and the record otherwise reflects a deliberate and clear rationale for EPA's direction, including consideration of perspectives presented by the Lower Willamette Group.

Given that this has already been a lengthy process, I believe it advisable for me to make decisions regarding fish consumption scenarios rather than allowing more time for the parties to work toward resolution. Although the exact RME scenarios may be relatively new as concrete proposals, the building block information has been available for quite some time and there has been ample opportunity for input and information exchange. Therefore, working from the exchanges of proposals during the informal dispute period and the Lower Willamette Group's November 13, 2012, response to my questions following on the oral presentations, I will focus separately on the recreational and subsistence fisher scenarios. There is some interplay in the selection of values for the various factors that are combined to create the overall exposure scenario, but at this point the ranges of differences are such that I can focus on areas of remaining differences only and be assured that the scenarios are consistent with guidance. The agreed 30-year duration of exposure and assumption of no effects from preparation/cooking methods will be applied for both the Recreational and Subsistence Fisher scenarios.

A) Recreational Fishers

Consumption Rate: The 17.5 g/day rate, considered in the guidance as an average rate for sport fishers, represents a good fit for the central tendency (CT) scenario. However, particularly because the 17.5 g/day rate comes from a survey of both consumers and non-consumers, this rate doesn't fit logically in the design of an RME. EPA has relied upon the Columbia Slough creel survey in proposing a 73 g/day consumption rate, using the assumption of 75 percent of the body weight of the fish. Because the survey results support the notion that some fishers near Portland Harbor sometimes consume more than just the fillet (estimated at 30 percent of the body weight), using a consumption value higher than that for fillet alone seems reasonable as part of an RME to account for this variation in the portion of the fish consumed. As EPA acknowledges in its "Response," information from numerous other fish surveys suggest sport fishers primarily consume fillets. Taking this collection of inputs into account, I turn to the Columbia Slough survey results' presentation of rates for consumption at a midpoint, where 50 percent body weight consumption is assumed. From this information I direct the use of a consumption rate of 48.9 g/day, which equates to approximately 6.5 meals per month. I note that this rate may, in fact, underestimate the rate for some recreational fishers based upon the survey, but this midpoint value strikes a reasonable balance given the limitations of the creel survey.

Tissue Type: In commenting on EPA's proposed RME fish consumption rate, and specifically in proposing a rate of 29 g/day, the Lower Willamette Group suggests that if one relies upon the Columbia Slough survey, the consumption rate value should be aligned with the assumption of the tissue type. Seeing the logic of this comment, I am inclined to require the use of an explicit "mixed diet" as part of the scenario, e.g. 2 meals per month whole body and 4.5 meals per month fillet, to arrive at the "effective" consumption of 50 percent body weight on average. However, so as not to further complicate things, I direct instead the use of fillet with skin (as agreed by the parties), with the assumption that using the 50 percent body weight value compensates some for the tissue type consumption variability. The text should explain in a quantitative or semi-quantitative way how the risks of fishers who consume more than just the fillet would be different as the mix of their diets varied.

Species Consumed: Although some recreational fishers pursue only particular fish, the Columbia Slough survey supports the notion that in the area of Portland Harbor, there are fishers who are not so discriminating. Therefore, a multi-species diet is more appropriate for an RME scenario. This assumption also seems to be better aligned with the mid-range consumption rate selected above, i.e. sustaining the rate is more plausible using multiple species than a single species. Based on the rationale presented by EPA, the smallmouth bass shall be used as the surrogate for the multi-species diet on a river-mile scale. The rationale needs to be clearly presented in the text for the benefit of readers who typically pursue and/or keep certain types of fish.

Exposure Area: The Lower Willamette Group expresses concern about the viability of the consumption rates when the exposure area is small. They also argue that fishers are likely to move beyond a one-mile reach. At the same time, in its proposal, the Lower Willamette Group puts forth a single river-mile exposure area for smallmouth bass. Given the concerns otherwise raised by the Lower Willamette Group, it makes sense to add the harbor-wide scale to provide a comparison and to capture both those fishers that may concentrate in one area and those that range more broadly. Therefore, the scenario shall include both river-mile and harbor-wide calculations.

So, in summary, with respect to the key exposure factors presented as part of the dispute, I direct the following for the Recreational Fisher scenarios:

CT:

- 30-year exposure duration
- No effect from preparation/cooking method
- Consumption rate of 17.5 g/day
- Fillet tissue with skin
- Multi-species diet; smallmouth bass as surrogate for river-mile scale
- River-mile as well as harbor-wide scale

RME:

- 30-year exposure duration
- No effect from preparation/cooking
- Consumption rate of 48.9 g/day
- Fillet tissue with skin
- Multi-species diet; smallmouth bass as surrogate for river-mile scale
- River-mile as well as harbor-wide scale.

B) Subsistence Fishers

First, the Recreational Fisher RME scenario summarized above shall suffice as a mid-point scenario, so no additional Subsistence Fisher CT scenario will need to be developed or used.[2] As to the Subsistence Fisher RME scenario, in addition to the agreed factors identified above, the parties agreed during the informal dispute on all of the key factors except tissue type. Again, the information from the Columbia Slough survey supports a scenario that incorporates consumption of more than just fillets, including whole body (or nearly whole body) use in soup. To the extent the Lower Willamette Group has asserted that the survey is more representative of a survey of Subsistence Fishers, the assumption of consumption of more than just fillets aligns even better with a Subsistence Fisher RME scenario. I disagree with the Lower Willamette Group's contention that the fish consumption rate offsets the assumption that only fillets are eaten, but I would agree that it is unnecessary to assume whole body consumption. Therefore, as with the Recreational Fisher scenario, the Subsistence Fisher RME scenario shall be based upon fillet with skin consumption, but the text shall reflect the local information that supports more than fillet consumption. Specifically, both the exposure assessment and risk characterization text should note that although the Subsistence Fisher RME scenario does not explicitly include other than fillet with skin consumption, it is expected that some fishers consume more than just fillets, and that some may do so to a significant degree. The text in the risk characterization discussion also shall describe quantitatively, using calculations based upon available whole-body data, the impact on risks to Subsistence Fishers who incorporate more than just fillet consumption into their diet.

In summary, the Subsistence Fisher scenarios shall be as follows:

CT:

- No separate scenario developed

[2] While the consumption rate for the Recreational Fisher for the RME scenario is now lower, the rate is still high enough that, as had been agreed to previously by EPA, no separate Subsistence Fisher CT scenario is necessary.

RME

- 30-year exposure duration
- No effect from preparation/cooking
- Consumption rate of 142 g/day
- Fillet tissue with skin
- Multi-species diet
- Harbor-wide scale

2) "EPA's June 2012 directed redline fails to comply with EPA guidance stating that a BHHRA must provide an adequate description of the actual risks relating to exposure to contamination."

Though titled more broadly, this issue really centers on the scenarios of the Willamette River as a domestic water source and the consumption of clams (especially Asian clams). Rather than attempt to resolve the merits of the Lower Willamette's Group's contention regarding EPA's June 2012 version of the BHHRA, I begin by noting that, as both parties acknowledge, the September 17, 2012, version of the BHHRA includes all or nearly all of the language requested by the Lower Willamette Group with respect to both domestic water use of the Willamette River and clam consumption. To the extent that not all of the Lower Willamette Group's desired language is included, I find that the language that *is* included sufficiently makes their point about the legal/regulatory context of these scenarios, and the implied (or more than implied) likelihood of the exposures they represent.

What are really in dispute is where various portions of the language should go and possibly how many times it should be repeated. For the benefit of the reader of the BHHRA, I find that the most effective presentation would bring all information (whether "uncertainty" or "context") about these two topics presented as red-lined text in Sections 6.2.2.3 and 6.2.3 forward into appropriate locations in Section 3 (specifically 3.2 and 3.3.6, respectively). In this way, the reader will have the benefit of closely related discussions in one continuous section rather than reading half the story in one location and the other half in another. Section 6 should not repeat any of the information presented in the Section 3 subsections, and there should instead be appropriate cross references from Section 6 to the appropriate subsections of Section 3. Because neither of these matters relates to a primary risk at the site, the current summary section appropriately does not repeat any of this information. Consideration of treatment in the executive summary can be taken up during its drafting, but for the same reason it seems unlikely these scenarios would warrant much, if any, discussion there, either.

3) "EPA's decision to not include a table of contents, executive summary, or conclusion in the BHHRA is inconsistent with EPA policy and guidance and significantly impairs public review and input."

As is now clear from their submissions, there was a misunderstanding between the parties about the intent of EPA's redlining, not a bona fide dispute as to whether the final BHHRA should have a table of contents and executive summary. Both of these elements of the document should be developed after other revisions to the document are completed. With respect to a conclusion section, I do not find the Lower Willamette Group's description of an intended conclusion section distinguishes it sufficiently from the summary section to warrant the inclusion of a separate conclusion section. There are or will be sufficient presentations (including summaries that include significant findings and conclusions) of the

information elsewhere in the BHHRA and in the broader RI/FS. EPA guidance and policy do not require a conclusion section in the BHHRA, and the Lower Willamette Group has not presented a convincing case that the absence of the proposed conclusion section will "significantly impair" the public's review and comment.

Finalizing the BHHRA

As a final matter, I will now address how the parties shall incorporate this Final Resolution into the BHHRA.

The parties have expressed similar expectations in terms of the time needed to finalize the BHHRA moving forward from this point (approximately forty-five days plus final review). I hereby adopt EPA's attachment to its November 13, 2012, response referred to as "List of Tasks to complete BHHRA 11-07-2012.pdf" by file name, and alternatively entitled on its face as "Basis for time to complete BHHRA," with the following modifications:

1) Consistent with my request, EPA included its assumptions, of which there are eight. My resolution does not fully track with either scenario described in the first assumption. Given the magnitude of the changes called for in my resolution, however, I do not believe incorporating these changes should require more than one additional day. I assign this task to EPA to complete concurrent with its work on Tasks 1 and 3, with the same process for Lower Willamette Group review and EPA finalization (i.e., ten days for Lower Willamette Group review and comment; one day for EPA to consider comments and finalize).
2) As a clarification to EPA's sixth assumption, the Lower Willamette Group shall have the right to dispute EPA final decisions on text on the basis that the disputed text is inconsistent with this Final Resolution.
3) In consideration of the date of this Final Resolution, the Lower Willamette Group shall be afforded sixty days rather than forty-five days to complete Tasks 2 & 4 through 22; incorporate Tasks 1 & 3 and Modification 1, above, from EPA; and submit a revised version of the BHHRA to EPA.

Attachment: Administrative Record Summary

EXHIBIT 7

From:	Wyatt, Robert
To:	Deb Yamamoto
Cc:	Chip Humphrey; Elizabeth Allen; jim.mckenna@verdantllc.com; Jennifer Woronets; Kristine Koch; Sheila Fleming; Lori Cora; Steve Parkinson
Subject:	Confirmation of Extension for Informal Dispute Resolution
Date:	Wednesday, August 01, 2012 3:29:59 PM

Deb:

Per our informal dispute resolution settlement meeting yesterday, we have confirmed with the LWG technical team that we can provide EPA with our comments on unacceptable substantive changes made to the Baseline Human Health Risk Assessment by Wednesday, August 15th. With the 30 day extension of the informal dispute resolution period to September 7, 2012 that we discussed. This allows three weeks for the parties to work through these issues and see if an agreement is possible. We trust that this is sufficient time and that the 30 day extension of the informal dispute resolution period is hereby approved. Please confirm by reply email.

We also want to confirm our agreement that the 30 day extension is without prejudice to any claims or defenses in this dispute by either party.

Lastly, we want to confirm our agreement yesterday that written communications between EPA and the LWG during the informal negotiation period will be maintained as settlement confidential consistent with FRE 408, as will oral communications concerning the substance of our settlement negotiations. As we are sure EPA is aware, there has been substantial media coverage of EPA's determination that the BHHRA was deficient and that the LWG is in violation of the Consent Order, and the LWG and its members will continue to respond to such coverage as we deem appropriate.

Thank you,

Bob

EXHIBIT 8

EPA Conditional Approval of RI/FS Work Plan
March 15, 2004

Condition 3 - Text changes to the RI/FS Work Plan:

The following text changes are based on review of the February 27, 2004 and March 5, 2004 redline versions of the Work Plan, discussion and agreements during our March 3, 2004 meeting and subsequent discussions between the U.S. Environmental Protection Agency (EPA) and the Lower Willamette Group (LWG). In general, comments are limited to the LWG's response to EPA's February 11, 2004 comments on the Work Plan and subsequent language changes. However, a small number of additional comments have been included.

February 27, 2004 Redline:

In general, the February 27, 2004 redline of the Work Plan adequately addressed the majority of EPA's previous comments. Several directed changes below address responses that did not fully resolve EPA's February 20, 2004 work plan comments. The comments reference comment numbers as provided in the LWG's February 27, 2004 response to EPA's comments and the appropriate section of the Work Plan. EPA directs the LWG to make the changes as specified below:

General Comment 11, Site Use Factors: Appendix B, Section 5.3, Assessment Endpoint No. 5 and 6 should be revised to state that site use factors of 100% will be used unless sufficient supporting documentation is provided to justify site use factors of less than 100%.

General Comment 13 - Sources of Contamination: The following paragraph should be inserted into Section 6.2 (Objectives of the RI/FS): "Sources of contamination to Portland Harbor may contribute localized areas of risk exceeding acceptable levels. Sources include storm water discharges, groundwater discharges, atmospheric deposition and non-point source runoff. If it is determined that these sources contribute to unacceptable risk to the site, a combination of upland source control measures and in-water remediation measures will be required. The RI/FS must gather sufficient data for the human health and ecological risk assessments to evaluate the risks associated with the release, discharge or emission of these sources to Portland Harbor."

General Comment 14, Interim Risk Evaluations: The following statement should be inserted into Section 6.2: "Interim risk evaluations will be used to focus the remedial investigation. These interim risk evaluations will be based on conservative exposure assumptions and will consider all relevant RI/FS data to understand whether (and under what conditions) receptors may be exposed contaminated subsurface sediment above acceptable levels."

General Comment 21, Conceptual Site Model: The following language should be inserted into Section 1.3.2, Overview of the RI/FS Tasks - RI Scoping Process:

A Conceptual Site Model (CSM) will be developed that portrays the relationship among sources, chemicals, transport mechanisms (including sediment transport, surface runoff and groundwater discharges to the Site), receptors, and other parameters that are determined to be relevant.

A CSM will be submitted in accordance with the approved schedule. The purpose of the CSM is to:

1. Focus sampling.
2. Gain a better understanding of potential contaminant loadings from upland sources (including direct discharge, overland transport, groundwater and bank erosion) and the relative importance of the various transport mechanisms in different river miles.
3. Identify where there may be continuing sources of contamination and pathways to the river (including persistent bioaccumulative toxins) based on historical site use information, site information and analytical data.
4. Identify historical sources of contamination and pathways to the river.
5. Identify overwater activities that may have released contamination to the Willamette River sediments.
6. Identify areas of the river where recontamination of sediments by upland and other sources is a risk.
7. Gain insight regarding upland source control strategies and help DEQ identify where additional work must be done by responsible parties and DEQ on upland sites.

Comment 25, Section 1.3.3, RI/FS Reporting: EPA acknowledges that this section will need to be revised based on resolution of the project schedule. The revised language should include the following: "As specified in the Administrative Order on Consent (AOC), analytical data will be provided to EPA within 60 days of each sampling activity (e.g., Round 2 surface sediment sampling, Round 2A sediment coring, Round 2B sediment coring, sediment beach sampling, surface water sampling, groundwater pathways sampling, natural attenuation sampling, Round 3 sampling and any other sampling activity). Data will be included in a field sampling report for each sampling effort. Data will be provided in electronic format showing location medium and results. Data will be provided in sufficient detail for EPA and its partners to begin preliminary analysis."

Please note also that EPA expects that the project schedule will include a site characterization summary (including data gaps analysis) that will be provided to EPA within 120 days after completion of field sampling and analysis as specified in the AOC. Site characterization summarys will serve as the basis for identifying data gaps and focusing subsequent phases of the investigation.

Comment 26, Section 1.4, Cultural Resources: EPA anticipates providing specific direction to Respondents by March 19, 2004.

Comment 27, Section 1.5, Community Relations: All but the first sentence in the second paragraph of this section should be deleted.

Comment 29, Section 2.1.5, Groundwater Transition Zone: The term transition zone should replace the term porewater through the Ecological Risk Assessment work plan (Appendix B).

Comment 36, Section 4.5, Summary of Human Uses: The fourth sentence in the second to last paragraph of this section should be revised to read: "A news story by the Oregonian and limited

interviews conducted by ATSDR suggest that groups likely to be catching and eating fish from the LWR *include* immigrants from Eastern Europe..."

Comment 43, Section 6.0, Overview of Portland Harbor RI/FS Process: The paragraph following the bullets should be revised to read: However, additional sampling rounds may be required to address data gaps identified as a result of technical memorandum development, review of Round 1 data, round 2 data or review of relevant new data or information.

Comment 44: Section 6.1, Preliminary RAOs: Data regarding recreational and subsistence fishery use is not being collected as part of the RI/FS. Delete the reference to recreational and subsistence fishery data in this section. In addition, sediment toxicity data should be added as a data category.

Comment 46, Section 6.2, Objectives of the RI/FS: The newly inserted sentence should read: Additional data collection may also be required to address data needs identified in subsequent TMs, data gaps identified during sampling rounds 2A and 2B and/or new information relevant to the RI/FS.

Comment 51, Section 6.3.1, Scope of Upstream and Downstream Sampling: This section should be revised to state that a Technical Memorandum will be submitted on this issue.

Comment 61, Section 8.4.4, Facility Siting Tasks: The following sentence should be added to the last paragraph of this section: "It is anticipated that early outreach on the proposed disposal site list for FS evaluation may be conducted to help understand the range of potential public opinion on the sites." In addition, delete all language following "aquatic resources." in the last paragraph of Section 8.8 and replace with "Thus, the remedial alternatives will need to have some early assessment of the magnitude of mitigation and its cost to run through the nine criteria evaluation."

Comment 64, Section 8.6.4, Define Preliminary SMAs and Volumes: The principal threat evaluation is the appropriate mechanism to develop the concept of "high" and "low" risk areas. The relevant sentences should read:

> "The general magnitude of risks as described in the ERA and HHRA documents will also be considered using information such as hazard quotients, risk probabilities, and other risk estimates. so that areas of relatively "high" and "low" risks can be defined. Note that these designations are not intended to imply any regulatory designation (which can only be applied by EPA), but rather are a means to understand how risks vary spatially across the site. The LWG will coordinate closely with EPA on the mapping of risk areas and how this information is finally presented in the FS. The identification of principal threat areas will assist in the evaluation of remedial alternatives that may better address areas of particularly concentrated or toxic chemicals that differ in character from other SMAs or the Site in general."

Comment 67, Table 7-11, The DQO Process for the Human Health Risk Assessment: Under Step 2, delete "in the ISA" and replace with "in the Site".

Comment 73, Table 7-11, The DQO Process for the Human Health Risk Assessment: Under Step 4 change "In-water surface sediments collected in Round 2 in areas within the Site where fishing occurs or commercial diving has been documented" to "Selected in-water sediments collected in Round 2".

Comment 87, Appendix B, Section 2.5.3.4: The work plan should state: "If lamprey are observed during sediment sampling, they should be collected and held for possible analysis. If sufficient tissue mass is obtained, a plan for sample analysis will be developed in cooperation with EPA."

Comment 101, Attachment B-7: Section 5.3, Assessment Endpoint No. 2 was apparently revised in response to this comment. However, the language provided is confusing on how invertebrate tissue concentrations will be estimated. The ecological risk assessment technical memorandums and/or the food web technical memorandums must include an approach for estimating invertebrate tissue concentrations through modeling and/or data collection.

March 5, 2004 Redline:

A number of changes have been made based on the outcome of our March 3rd meeting. Some of this language was developed during subsequent discussions between EPA and LWG representatives. The following changes reflect either language agreed to by EPA and the LWG or reflect review of the March 5, 2004 Redline version of the Work Plan.

Section 6.2 - Objectives of the RI/FS: The sentences that refer to chemicals entering the ISA should be revised to read: "Chemicals may be entering the ISA from sources located within the ISA or upstream of the ISA, and some chemicals may be contributed from both ISA and upstream sources. Background levels will be established in accordance with EPA (2002c) and other relevant guidance and will be used in the overall remedial decision-making for the Site. The approach that will be used to establish background levels will be submitted to EPA for review as a technical memorandum. It is anticipated that consideration of background conditions would follow EPA guidance (2002) on this subject as well as other relevant EPA Superfund guidance and regulatory and statutory requirements."

Section 6.3.2 - Define Background Conditions:

This section should be revised to read: "Background conditions are typically considered to make appropriate risk management decisions, and will be considered in the FS. Evaluation of background conditions will be performed in conjunction with EPA and EPA guidance on this subject (EPA 2002) and other relevant EPA Superfund guidance. Site-Specific background conditions for various data types (e.g., sediment chemistry, sediment toxicity, surface water chemistry) will be identified in a future technical memorandum as noted in Sections 6.2 and 7.3.4."

Section 6.4.3 - Ecological Risk Assessment Scoping Activities:

This section should be re-written to list the purpose, content and production schedule of each Ecological Risk Assessment Technical Memorandum. Each of the elements described in EPA's

February 11, 2004 comments on the programmatic work plan (General Comment - Ecological Risk Assessment Work Plan) must be incorporated into the technical memorandum process. In addition, methodologies for estimating invertebrate tissue concentrations must also be described.

Section 6.4.4, Round 2 Work:

The new language added regarding the Round 2 Data Evaluation should be revised to read: "As specified in the Administrative Order on Consent (AOC), Round 2 analytical data will be provided to EPA within 60 days of each sampling activity (e.g., Round 2 surface sediment sampling, Round 2A sediment coring, Round 2B sediment coring, sediment beach sampling, surface water sampling, groundwater pathways sampling, natural attenuation sampling). Data will be a field sampling report for each sampling effort. Data will be provided in electronic format showing location medium and results. Data will be provided in sufficient detail for EPA and its partners to begin preliminary analysis. A site summary characterization summary (including data gaps analysis) will be provided to EPA within 120 days after completion of field sampling and analysis as specified in the AOC. Site characterization summarys will serve as the basis for identifying data gaps and focusing subsequent phases of the investigation."

Section 7.2.2. - Surface Water:

This section should be revised to read:

7.2.2 Surface Water

Surface water samples will be collected to identify potential sources, to understand the distribution of chemicals resulting in potentially unacceptable ecological and human health risk (described in Sections 7.3 and 7.4), and to understand the potential for recontamination for the FS (described in Section 8).

The DQO process for understanding the distribution of chemicals in surface water is summarized in Table 7-4.

Problem Description

There is little existing water quality data for the ISA. Therefore, the objectives of the water sampling program are to assess water quality conditions in the ISA under different flow conditions, provide water quality data for use in the ecological and human health risk assessments, and provide water quality data for the assessment of recontamination potential during the FS.

Data Uses

Surface water data will be used to determine:

- If upland sources in the ISA are contributing to unacceptable risk from river water
- Support for the ecological and human health risk assessments
- If various river stages and flows and storm events have a measurable effect on the nature or concentration of surface water chemical constituents

- The impact to the ISA of potential upstream sources of surface water chemical constituents
- The potential presence of natural attenuation processes within the ISA
- The potential for recontamination of remedial alternatives (examined in the FS).

Data Needs

Sampling and analytical methods must be adequate to achieve detection limits that are below risk-based water quality screening levels. Sampling will be conducted during an early fall "first flush" stormwater runoff event and both low-flow and high-flow river conditions. Sample location and density must be adequate to assess variation in chemical concentrations in surface water immediately upstream, downstream, and within the ISA. Sample location and density must also be adequate to understand the potential for source effects to river water and sediments.

RI/FS Tasks

A tiered approach to the water quality investigation is proposed. Surface water sampling was proposed by the LWG but not approved by EPA in Round 1. In Round 2A, surface water samples will be collected using high-volume sampling methods at three transects: one transect at RM 11 above the upstream boundary of the ISA, one transect at RM 6 within the ISA, and one transect at RM 3.5 at the lower boundary of the ISA. Upstream samples will be used to evaluate the upstream contribution of chemicals to the ISA. High-volume samples also will be collected at four locations (Rhone Poulenc, Willamette Cove, Atofina and Portland Shipyard) during an optimum-flow sampling event to assess potential source effects. Grab samples will be collected to support the ERA. Grab samples will also be collected in potential swimming areas to support the HHRA.

Specific Round 2A water quality sample locations, analyses, collection methods, and required analytical detection limits will be provided in the Round 2 surface water sampling FSP. High-volume surface water sampling methods will achieve minimum reporting limits below chronic and acute Ambient Water Quality Criteria (AWQC) and Oak Ridge National Laboratory ecological screening values and below AWQC for the protection of human health and EPA Region 9 PRGs. Grab sampling methods will achieve minimum reporting limits below chronic and acute AWQC and Oak Ridge National Laboratory ecological screening values and below EPA Region 9 PRGs for all COPCs except N-nitrosodimethylamine, toxaphene, and dioxins/furans. These criteria are used to identify analytical reporting limits and for screening purposes.

Additional surface water samples will be collected in Round 2B for analysis of persistent, bioaccumulative toxins (PBTs) using high-volume sampling methods if a data gaps analysis based on Round 2A sampling results, the ecological preliminary risk evaluation, food web modeling results, and groundwater impacts evaluation scoping determines that additional surface water data with very low minimum reporting limits are needed to develop PRGs or evaluate source effects. Similarly, if additional surface water sampling to determine chemical distributions, source effects, natural attenuation, or recontamination potential is necessary, the proposed approach will be presented in a Round 3 FSP.

In addition, Table 7-4 must be revised accordingly to reflect the described approach.

Section 8.2 Remedial Action Objectives:

The Fifth paragraph of this section should be revised to read: The five preliminary RAOs listed in Section 6.1 all follow the specific requirements of RAOs in EPA (1988) guidance. The FS will consider "background" following EPA guidance (EPA 2002) on the use of background in RI/FS evaluations and other relevant EPA Superfund guidance.

Section 2.5 - Attachment A-1 of FS Work Plan (Appendix A):

The last paragraph of this section should read:

These preliminary RAOs all follow the specific requirements of RAOs in EPA (1988) guidance. Preliminary RAOs will be refined as the project moves forward. It should be noted that reference to background may be considered in coordination with EPA in the FS. The FS will consider "background" following EPA guidance (EPA 2002) on the use of background in RI/FS evaluations and other relevant EPA Superfund guidance.

Appendix B, Section 2.3.2.2:

Narrative language regarding sturgeon was agreed upon by EPA and the LWG for Appendix C of the Programmatic Work Plan. Identical language should be inserted into Section 2.3.2.2 of Appendix B. The fifth paragraph of this section should be revised to read: "White sturgeon are found in the lower Willamette River, including in Portland Harbor. They are highly valued by tribes as a food source and for cultural uses. They are also highly valued as sport fish. The annual harvest of sturgeon from the lower Willamette River has been estimated to be from 1000 to 2000 fish (ODFW 2002). White sturgeon is the largest freshwater fish in North America and has a long life span. Some studies suggest that sturgeon can show strong site fidelity (Veinott et al 1999) while other studies indicate individual sturgeon can have large ranges (Devore and Grimes 1993)." In addition, the second to last sentence in paragraph 3 should be deleted and the last sentence should be revised to read: "All of the omnivorous species are predominantly bottom-feeders." The paragraph referring to green sturgeon should be revised to read: Another sturgeon species, which may be present in the Lower Willamette River, is the green sturgeon (*Acipenser medirostris*)."

Appendix B, Section 2.5.3, Fish Species: This section will need to be revised pending finalization of the Assessment Endpoint Table.

Appendix C (Various Sections):

This section needs to be revised as specified below. Most of these changes were previously agreed upon by EPA and the LWG:

Section 3.1.1 –

Additional potential use areas outside of the ISA were identified during 2003 and will be sampled as a part of Round 2 of the RI; these areas will be included in the human health risk assessment. Additional use areas may be identified during the RI/FS. For example, as a part of Round 2, beach samples are being collected in areas where shorebird exposure may occur. If credible information suggests that these beaches are or would become accessible to and used by humans, these shorebird beaches will be designated as human use areas and evaluated for the appropriate scenario.

Section 3.3.4.3 –

Pacific lamprey are harvested by Native American Tribes primarily at Willamette Falls. Juvenile Pacific lamprey spend from 3 – 7 years in freshwater rivers and tributaries before transforming into adults (Kostow 2002). The preferred habitat of juvenile Pacific lamprey is muddy bottoms, backwater, and low gradient areas (Kostow 2002). Its main food source is microscopic biota obtained by filtering mud and water (Kostow 2002). This may result in high juvenile lamprey exposure to contaminants present in sediments. After transforming to the adult form, lamprey move into the ocean where they live as predators/parasites for an estimated 20 to 40 months on larger fish and whales before returning to fresh water for as long as a year before spawning (Kostow 2002).

Sturgeon
White sturgeon are found in the lower Willamette River, including in Portland Harbor. They are highly valued by tribes as a food source and for cultural uses. They are also highly valued as sport fish. The annual harvest of sturgeon from the lower Willamette River has been estimated to be from 1000 to 2000 fish (ODFW 2002). White sturgeon is the largest freshwater fish in North America and has a long life span. Some studies suggest that sturgeon can show strong site fidelity (Veinott et al 1999) while other studies indicate individual sturgeon can have large ranges (Devore and Grimes 1993).

Sturgeon was not sampled as a part of the RI/FS Round 1 investigation. However, juvenile sturgeon were collected within the Portland Harbor site in July, 2003, as a part of the cooperative effort by ODHS, ATSDR, ODFW, the City of Portland, and USEPA, Region 10.

The potential risk to Native American consumption fishers resulting from consumption of salmonids, lamprey, and sturgeon will be included in the risk assessment by including these species in a multiple species diet along with resident fish. This multiple species diet will be based upon tribal consumption information in the CRITFC Fish Consumption Report. The risk assessment will include a discussion of the uncertainties in determining the chemical body burden in sturgeon, salmon, and lamprey resulting from exposure to COPCs from the Site.

The use of adult salmon, lamprey, and sturgeon in the risk assessment is intended to provide a more complete picture of exposure to persons ingesting fish harvested from the ISA. However, the source of COPC concentrations in the tissues of adults from the Site for such species may be difficult to determine because of their life history and habits.

Section 3.4.3
Tissue EPCs will be estimated for resident species and for lamprey, salmonids, and sturgeon. The EPCs for lamprey, salmonids, and sturgeon will be used to evaluate risks to Native American consumption fishers in a multiple species diet. The fish consumption evaluation will be based on a range of fish consumption rates. Because these consumption rates will not be designated as representing either RME or CT exposures the EPCs for tissue will not be developed specifically for RME or CT scenarios. The process to estimate tissue EPCs is described below.

3.4.3.1 Resident Species

Data from uncooked resident fish and shellfish samples collected during Round 1 and any subsequent investigations will be used to estimate the EPCs for tissue. Historic tissue data selected for use in the HHRA (see Section 2.1) will also be used to estimate EPCs for tissue. EPCs will be estimated only for individual fish and shellfish species that are consumed by fishers in the area. EPCs for fish will be calculated for both fillets and whole bodies.

EPCs for tissue will be estimated both for individual sampling locations and for the entire Site. EPCs will be estimated by location for crayfish, by river mile for bass (due to their small home range), and by fishing zone (defined as RM 3-6 and RM 6-9, representing the upper and lower ends of the ISA) for carp, crappie, and bullhead, since these fish have larger home ranges than bass. EPCs for fish will be estimated for each species.

Replicate composite samples were collected for each fishing zone for carp, crappie, bullhead, and at three of the eight river mile stations for bass. The replicate composite samples will be averaged and the arithmetic mean concentrations will be used as EPCs for individual sampling locations. To address potential variation in tissue concentrations, the maximum composite results for each fishing zone and at the three river mile segments will also be used as EPCs for individual sampling locations. The uncertainty associated with using the average and maximum concentrations as EPCs will be discussed in the risk assessment.

At the one-mile river stations where replicate composite samples were not collected for bass, the results of the single composite sample will be used as EPCs for these stations.

Site-wide tissue EPCs will also be estimated using mean concentrations and 95 percent upper confidence limit (UCL) on the average or maximum composite results. Where sufficient data are available, the 95% UCLs will be calculated using an approach agreed to by the LWG and EPA and its partners, and the 95% UCLs will be used as site-wide EPCs. If sufficient data are not available, the maximum composite results will be used as site-

wide EPCs. In addition, the arithmetic mean of individual sampling location EPCs will be used as site-wide EPCs.

3.4.3.2 Lamprey, Salmonids, and Sturgeon

Data from uncooked fish samples collected as a part of the ODHS study and any subsequent investigations will be used to estimate the EPCs for tissue for use in a multiple species diet that is based upon the proportion of fish consumed in the CRITFC Fish Consumption study. For sturgeon (fillet without skin), site wide EPCs will be calculated. For lamprey (whole body) and Chinook salmon (whole body and fillets), the EPCs will be estimated using the composite samples collected at Willamette Falls and at the Clackamas Hatchery, respectively. Site-wide EPCs calculated for resident species will be included in the multiple species diet.

Because it is currently not known exactly what tissue data are available, the process to estimate EPCs for lamprey, salmonids, and sturgeon will be developed at a later date, in cooperation with EPA and its partners. This process will be consistent with the methods used for developing EPCs for the resident species.

Section 3.4.5.1 –
arsenic speciation analysis of the fish tissue. Regardless of the risk characterization

Section 3.5.1.4 –

For the tribal scenario, a multiple species approach will be done using the fish consumption data from the CRITFC Fish Consumption study (CRITFC 1994) with concentration data from the target resident species as well as from sturgeon, salmon and lamprey caught as a part of the ODHS sampling effort. The risk assessment will include a discussion on the uncertainty in estimating the proportion of contaminants in sturgeon, salmon and lamprey and associated risks that result from contaminants at the Site.

3.5.1.4 Fishers

The HHRA will use different fish ingestion rates encompassing the 3 fisher scenarios selected: recreational fisher; high consumption non-tribal fisher; and Native American consumption fisher. Consumption of resident fish species will be evaluated for the recreational fisher and high consumption non-tribal fisher scenarios. A multiple species diet that includes resident fish as well as salmonids, lamprey, and sturgeon will be evaluated for the Native American consumption fisher scenario. Consumption of crayfish will be evaluated separately. The approaches that will be used to evaluate these consumption scenarios are discussed below.

The approaches discussed below are based on information currently available. In the case that additional information becomes available prior to the HHRA, it will be discussed with EPA and its partners as to if and how it will be used in the risk assessment.

Resident Fish Species

Site-specific fish consumption information is not available for the recreational fisher or high consumption non-tribal fisher scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist for these receptors, 3 ingestion rates will be used to calculate intakes for adults and 3 will be used for children. For adults, the fish ingestion rates that will be used in the HHRA are 17.5 grams per day (g/day), 73 g/day, and 142 g/day. The corresponding rates that will be used for children are 7 g/day, 31 g/day, and 60 g/day. These ingestion rates are anticipated to represent average to high end ranges of fish consumption for these receptors.

Two of these rates, 17.5 g/day and 142 g/day, represent the 90th and 99th percentile ingestion rates for freshwater and estuarine fish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002). Because these rates are from a national dietary study, they may not be representative of site-specific consumption patterns. The other ingestion rate, 73 g/day, is from a creel study conducted in the Columbia Slough and is the 95 percent upper confidence limit on the average for ingestion of fish where 75 percent of the total fish is consumed (Adolfson 1996). While this study may be more representative of consumption patterns for the Site, the study was limited in scope and the reported ingestion rates were estimated based on numerous assumptions. The uncertainties associated with each of the fish ingestion rates will be discussed in the HHRA.

For the recreational fisher and high consumption non-tribal fisher scenarios, the risk assessment for the target resident fish species (bass, black crappie, bullhead, and carp) will be done using the ingestion rates for these two scenarios with concentration data on each individual resident species (for whole body and fillet tissue). EPCs will be calculated for fishing zones (carp, crappie and bullhead) and mile reach (bass) as well as for the entire Site, as described in Section 3.4.3. In addition to the individual species diet, multiple species diet will also be done for these two fisher groups by using the fish ingestion rates for the scenarios with the concentration data of all resident species (for whole body and fillet tissue) for the Site (i.e., a multiple species diet assuming that each of the 4 fish target species represents 1/4 of a person's diet). The following scenarios will be evaluated for each of the above ingestion rates.

	River Mile	**Fishing Zone**	**Entire Site**
Smallmouth bass	X[1]		X[3]

Black crappie		X^2	X^3
Carp		X^2	X^3
Brown bullhead		X^2	X^3
Multiple species			X^4

[1]Three replicate bass composites were caught at 3 of the river mile locations - EPCs will be calculated by river mile using the arithmetic mean of the replicate composites and also using the maximum concentration of each chemical in any of the 3 composites in each river mile (by body type). Where replicates were not collected, the results for the single sample will be used as the EPCs.
[2]Three replicate composites for crappie, carp and bullhead were caught at fishing zones 3 to 6 and 6 to 9; EPCs will be calculated for the 3 to 6 mile reach and for the 6 to 9 mile reach using the arithmetic mean of the replicate composites and also using the maximum concentration of each chemical in any of the 3 composites in each reach for each species (by body type).
[3]EPCs will be calculated using the arithmetic mean of the replicate composites and also using the maximum concentration of each chemical in any of the composites caught in the entire site.
[4]EPCs for multiple species will be calculated using the EPCs calculated for individual species in footnote 3 (by body type).

Tribal Multiple Species Diet

While site-specific fish consumption information is not available for the Native American fisher scenario, a fish consumption survey was conducted on the reservations of four of the participating Tribes (CRITFC 1994). The 95th percentile fish ingestion rate from the CRITFC Fish Consumption study, which is 175 g/day, will be used to calculate intakes for adult Native American fish consumers. The corresponding rate of 73 g/day will be used for child Native American fish consumers.

For the tribal scenario, a multiple species approach will be done using the fish consumption data from the CRITFC Fish Consumption study (CRITFC 1994) with concentration data from the target resident species as well as from sturgeon, salmon and lamprey caught as a part of the ODHS sampling effort. The fish consumption information from the CRITFC study will be used to determine the ingestion rate for each fish species, as shown below:

Species	**Grams per day[1]**	**Percent of diet**

Species	Grams per day[1]	Percent of diet
Salmon	67	38.4
Lamprey	12.3	7.0
Sturgeon	8.6	4.9
Smelt	12.5	7.2
Whitefish	23.2	13.3
Trout	25.1	14.3
Walleye	9.9	5.7
Northern Pikeminnow[2]	3.7	2.1
Sucker	7.3	4.2
Shad	5.2	3.0
Total Ingestion Rate	175	100

[1]Grams per day are based upon weighted mean data in Table 18 of the CRITFC study.

[2] Squawfish is now called Northern Pikeminnow

Unless new data are collected, data from the 2003 ODHS fish sampling effort will be used to calculate EPCs for salmonids, lamprey, and sturgeon. As with the resident fish, the arithmetic mean of composites and the maximum concentration in any of the composites (for salmon and lamprey) will both be used as the EPCs. Sturgeon were collected as individual samples, so the arithmetic mean of the individual samples and the

maximum concentration in sturgeon samples will both be used as EPCs. The uncertainty associated with using the mean and maximum concentrations as EPCs will be discussed in the risk assessment.

For adult Native American consumers, the ingestion rates for salmonids (67 g/day), lamprey (12.3 g/day), and sturgeon (8.6 g/day) will be used with the respective EPCs for those species to calculate intakes. For the remaining species, each of the EPCs calculated for the entire Site for smallmouth bass, black crappie, carp, and brown bullhead will be used with an ingestion rate of 21.7 g/day (i.e., the ingestion rate for the sum of the species that are not salmonid, sturgeon or lamprey, 86.9 g/day, divided by 4). The combined intakes from salmonids, lamprey, sturgeon, and the remaining fish species in the above table will be used to estimate risks from fish consumption. The intakes for child Native American consumers will be calculated using the same dietary percentages as the adult Native American consumers, but with a total ingestion rate of 73 g/day.

The risk assessment will include a discussion on the uncertainty in estimating the proportion of contaminants in sturgeon, salmon and lamprey and associated risks that result from contaminants at the Site.

Crayfish

Site-specific crayfish consumption information is not available. For crayfish, only adult consumption will be evaluated. Ingestion rates of 3.3 g/day and 18 g/day will be used to calculate intakes from crayfish consumption. These values represent the average (3.3 g/day) and 95th percentile (18 g/day) ingestion rates for shellfish consumption from freshwater and estuarine systems for individuals of age 18 and older in the United States (EPA 2002). These ingestion rates will be used with EPCs calculated for each crayfish sample location as well as for the entire Site, which will include both the average and maximum concentrations of each chemical detected in any of the composites in the entire Site. The uncertainties associated with the crayfish ingestion rates will be discussed in the HHRA.

Other Comments:

Section 1.0, Introduction: Due to the reliance on the technical memorandum process to resolve key issues related to the work plan, the last sentence should be revised to read: "These memoranda will be submitted to EPA and its partners for review and approval, in accordance with the Work Plan schedule." Add additional sentence at end of paragraph: "Any EPA approved interim deliverable, addenda, or technical memorandum will be incorporated into this Work Plan and become a substantive part of this Work Plan under the AOC."

Section 1.3.2, Overview of RI/FS Tasks, Number 7: Add "as well as other data agreed to by EPA and the LWG" at the end of "The baseline risk assessments will be based on pre-AOC, Round 1, Round 2, and historic Category 1 data."

Section 2.1, Hydrogeology: The final sentence should read: The results of the groundwater review will be provided in the Conceptual Site Model report.

Section 5.3.2, Potential Exposure Pathways: After "Fishers may consume fish and shellfish that are caught from the Site and may also have dermal contact with, and incidental ingestion of, sediments at banks" add "and in water".

Appendix B, Section 5.3 - Assessment Endpoint 3: The text should include the following statement: "Chemical Concentrations in whole body tissues of each receptor of concern will be analyzed to determine exposure point concentrations for each fish species." In addition, text should be added that indicates the use of a 95% UCL applies only to a dietary analysis and not a tissue TRV analysis.

Appendix A, Attachment A-4, Section 1: The second and third sentences of the fourth paragraph of this section should be deleted.

Appendix A1 - Table 2: The following changes should be made:

i. The comment section for "Statement of Procedures on Floodplain Management and Wetlands Protection" last sentence should be revised as follows: "This includes City of Portland Ordinance, Ch. 24.50.060(D) & (F)(8), as those provisions implement federal law."

ii. Endangered Species Act - comment section last sentence must be revised to end after the word "services." Although the final ESA BA may be completed at the end of the RI/FS, we likely will need preliminary assessments and some consultation during development of the FS.

iii. National Historic Preservation Act - per prior comments, the last sentence of the comment section should be deleted. Although procedure is not required, the plan likely would be needed to implement substantive requirements of this ARAR.

iv. Environmental Cleanup Act -ORS 465.315 - Comment section. Revised last sentence as follows: "Where State regulations go beyond or are more stringent than federal law and regulations, State regulations are applicable or relevant and appropriate requirements. State regulations are not only ARARs if they are consistent or not more stringent than federal law.

EXHIBIT 9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 30 2011

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

MEMORANDUM

SUBJECT: Options for Responding to Deficient Deliverables from PRPs

FROM: Elliott J. Gilberg, Director
Office of Site Remediation Enforcement

TO: Superfund Division Directors, Regions I – X
Regional Counsel, Regions I – X
Superfund Program Branch Chiefs, Regions I – X
Superfund Regional Counsel Branch Chiefs, Regions I – X

As part of the Integrated Cleanup Initiative (ICI),[1] senior Superfund regional and headquarters managers met in October 2010 to identify and explore ways to address impediments to the timely completion of remedial action projects. One impediment identified by the managers was poor quality PRP deliverables that result in multiple rounds of EPA comments and PRP resubmission of revised deliverables.

When PRPs performing work at Superfund sites submit poor quality deliverables, EPA typically has a range of options. These include (but are not limited to) requesting revisions by the PRPs, unilaterally modifying the deliverable, assessing stipulated penalties, and making a referral to DOJ requesting judicial assessment of penalties. This memorandum discusses these options, recommends approaches that may facilitate EPA's ongoing efforts to ensure timely completion of PRP cleanups, and provides sample letters to PRPs that have submitted deficient deliverables.

One option for the Regions to consider is unilaterally modifying deficient deliverables to help limit response delays associated with multiple rounds of EPA comments and PRP resubmissions. EPA's model enforcement instruments generally include unilateral modification as an option when a Region receives a deficient deliverable. It may also be appropriate to assess stipulated penalties (or make a referral to DOJ requesting judicial assessment of penalties) based on case-specific factors. Factors to consider in gauging an appropriate enforcement response include the past compliance history of the PRPs (both as to prior obligations at the site and in responding to prior Agency comments on the current deficient deliverable), the degree of deficiency of the

1 The Integrated Cleanup Initiative is a three-year strategy to identify and implement improvements to EPA's land cleanup programs. More information about ICI is available on EPA's Web site at http://www.epa.gov/oswer/integratedcleanup.htm.

submitted deliverable, and the impact of the deliverable on the quality and timeliness of the cleanup.

Two sample letters for responding to inadequate deliverables are attached to this memorandum.[2] Given the many case-specific variables the Regions encounter in enforcing instruments that require PRPs to perform work, it is not possible to establish a uniform course of action that will apply in responding to every deficient deliverable. Consequently, the sample letters provide both base and alternative language for addressing initial and resubmitted deficient deliverables under common scenarios. It may be appropriate in light of case-specific circumstances for the enforcement response to a particular deficient deliverable to be more or less aggressive than the options provided in the sample letters. All such responses should clearly tell the PRPs both what EPA is requiring of them pursuant to the enforcement instrument and the consequences of failing to comply. Clear communication with PRPs facilitates timely compliance, reduces the likelihood of disputes, and creates a record for any subsequent enforcement.

The first sample letter ("Sample Letter – Comment on Initial Deliverable") notifies the Respondents/Settling Defendants that: (1) EPA does not approve their initial deliverable; (2) they must modify the deliverable in response to EPA comments; and (3) the Agency may exercise its right to unilaterally modify the next submission if the resubmitted deliverable does not adequately address EPA's comments. The sample letter also contains optional language notifying the Respondents/Settling Defendants that their submission of the deficient deliverable constituted a violation of the settlement and that stipulated penalties have begun accruing (or, if the deliverable was submitted pursuant to a UAO, that the Respondents may be subject to civil penalties).

The second sample letter ("Sample Letter – Modification of Resubmitted Deliverable") informs the Respondents/Settling Defendants that: (1) EPA is exercising its right to unilaterally modify a resubmitted deliverable; and (2) pursuant to the terms of the enforcement instrument, they are required to implement the modified deliverable. EPA may unilaterally modify a deliverable either by editing the deliverable and providing it to the Respondents/Settling Defendants or by directing them to make specified changes to the deliverable. Similar to the first letter, it also contains optional language notifying the Respondents/Settling Defendants that their submission of the deficient deliverable constituted a violation of the settlement and that stipulated penalties are accruing (or, in the case of a UAO, that EPA believes the submission constitutes a violation of the UAO and thus may result in civil penalties).

The sample letters are designed to be generally consistent with EPA's model enforcement instruments. However, not all model instruments contain the same provisions and model instruments are modified over time. Consequently, it is important that the regional personnel responsible for a site confirm that the language of a sample letter is consistent with the provisions of the applicable enforcement instrument in light of the facts of the case. The sample

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2 These are modified versions of sample letters attached to an OSRE memorandum from Charles Breece, dated July 1, 1996, and titled "Transmittal of Sample Documents for Compliance Monitoring."

letter should be modified to track the language of the applicable instrument whenever possible, and especially when the sample letter may be inconsistent with that instrument. The sample letters include notes identifying several particular circumstances where it is important to check that the letter is consistent with the terms of the enforcement instrument (*e.g.*, when discussing the accrual of stipulated penalties).

Although the sample letters address a scenario where EPA unilaterally modifies a resubmitted deliverable, the Agency also has the option of unilaterally modifying an *initial* deliverable under some enforcement instruments. The standard for such unilateral modifications may be different, however, from the one for modification of resubmissions. For example, EPA's model RD/RA consent decree allows the Agency to unilaterally modify an initial deliverable if EPA "determines that awaiting a resubmission would cause substantial disruption" to the work or "previous submission(s) have been disapproved due to material defects and the deficiencies in the initial submission under consideration indicate a bad faith lack of effort." The model RD/RA consent decree does not require EPA to make such a determination in order to modify a resubmitted deliverable.

Please note that, under some enforcement instruments, the Respondents/Settling Defendants may have the right to invoke dispute resolution in response to whichever tool EPA employs (*e.g.*, a request for modification of a deficient deliverable, unilateral modification of such a deliverable, or assessment of a stipulated penalty). Respondents/Settling Defendants may be more likely to invoke dispute resolution in response to a unilateral modification than to an Agency request for modifications. Given that such an invocation may in itself delay response activities, case teams should weigh any increased likelihood of the invocation of dispute resolution when deciding whether to unilaterally modify a deliverable. In addition, case teams should consider whether a concurrent assessment of stipulated penalties might be warranted given the case-specific situation. Finally, case teams should also bear in mind that while PRP invocation of the dispute resolution process may delay the specific response measure that is the basis of the dispute, it should not delay the PRPs' implementation of other, unrelated, response measures.

If you have any questions regarding the sample letters, please contact Steve Keim of my staff. Steve can be reached at 202-564-6073 or keim.stephen@epa.gov.

Attachments (2)

cc: Jim Woolford, OSRTI
ICI Superfund Managing Remedial Projects to Completion Workgroup

EPA United States Environmental Protection Agency

Sample Letter – Comment on Initial Deliverable

[Note: For use when the Respondents/Settling Defendants submit an initial deliverable that is inadequate. The sample letter includes optional language for assessment of stipulated penalties (for noncompliance with a settlement) and for possible statutory penalties (for UAO noncompliance).]

Name and address of contact for
Respondents/Settling Defendants

Re: Comments on **[name of document]**
[Name of Order/Consent Decree]
[Docket No.]
[Name of Site, City, State]

Dear Mr./Ms. **[name]**:

The U.S. Environmental Protection Agency (EPA) has completed its review of the **[insert name of document]** dated **[insert date]** for the **[insert name of facility]** Site located at **[insert address].** This document was submitted in accordance with the **[insert Order/Consent Decree]** between EPA and **[insert name of company/group].**

EPA disapproves the **[name of document]** as submitted, and requires **[insert name of company/group]** to amend the document in accordance with the attached comments. A revised **[insert name of document]** must be submitted within **[insert days]** days of your receipt of this letter as specified in **[insert section __ of the Order/Decree].** All of the enclosed comments must be addressed. If all comments are not adequately addressed, EPA may exercise its right to modify the document and provide the revised document to you for implementation or to direct you to make specified modifications to the document. **[RPM/Project Coordinator and/or ORC attorney should confirm that this statement is consistent with provisions of the applicable enforcement instrument and reference the applicable provision].**

If you believe that any changes are necessary other than those directed by EPA's enclosed comments, those changes must be discussed with, and approved by, EPA's Project Coordinator prior to re-submittal of the document. Those discussions may be memorialized in a progress report or other communication to EPA's Project Coordinator. In addition, all changes made to the document, other than those made specifically at the direction of EPA, must be specified in writing to EPA upon re-submittal of the document.

If you have any questions concerning this matter, or would like to discuss the attached comments in detail, please contact me at **[insert number]** or your legal counsel may contact **[insert name of EPA attorney]** at **[insert number].**

Sincerely yours,

[Insert name of Project Coordinator]

For noncompliance with AOCs or CDs, optional language to insert after paragraph 2: Please be advised that your submission of a deficient **[insert name of document]** constitutes a violation of the **[insert Order/Consent Decree]** and that stipulated penalties began accruing on the day after a satisfactory version was due to be received by EPA. Consistent with the provisions of the **[insert Order/Consent Decree]**, stipulated penalties will continue to accrue until the date that EPA receives a satisfactory version of the **[insert name of document]** from you. **[Some model instruments link "material defects" in a deliverable to the assessment of stipulated penalties; the RPM/Project Coordinator and/or ORC attorney should consider modifying the letter to match that language as appropriate.]**

For noncompliance with UAOs, optional language to insert after paragraph 2: Please be advised that EPA deems your submission of a deficient **[insert name of document]** to constitute a violation of the UAO and, as a result, you may be subject to civil penalties of up to $37,500 for each day this violation continues.

EPA
United States Environmental Protection Agency

Sample Letter – Modification of Resubmitted Deliverable

[Note: For use when the Respondents/Settling Defendants submit a revised document for Agency review and the document does not adequately address the Agency's comments. This sample letter informs the PRPs that EPA has unilaterally revised the resubmitted deliverable (with optional alternative language warning the PRP that EPA may unilaterally modify the deliverable in the future). The sample letter also includes optional language for assessment of stipulated penalties (for noncompliance with a settlement) and for possible statutory penalties (for UAO noncompliance).]

Name and address of contact for
Respondents/Settling Defendants

Re: Modification of **[name of document]**
[Name of Order/Consent Decree]
[Docket No.]
[Name of Site, City, State]

Dear Mr./Ms. **[insert name]**:

By letter dated **[insert the date of the comment letter to Respondents/Settling Defendants]**, the United States Environmental Protection Agency (EPA) disapproved **[insert name of company/group]**'s draft **[insert name of document]** dated **[insert date]** for your facility/site located at **[insert address of installation]** and provided you with comments identifying deficiencies. You submitted a revised **[insert name of document]** on **[insert date]**. Upon review, EPA has determined that the revised **[insert name of document]** does not adequately address the comments contained in EPA's **[insert date of comment letter]** letter. Accordingly, EPA disapproves the **[name of document]** as submitted and **[insert name of company/group]** is not in compliance with the **[insert Order/Decree]**.

Specifically, the **[insert name of company/group]** response of **[insert date]** failed to adequately address the following comments: **[Suggest listing each comment in EPA's comment letter that was not adequately addressed in the resubmitted deliverable. This could be followed by the Respondents/Settling Defendants' response or summary of the Respondents/Settling Defendants' response to the comment.]**

EPA is exercising its right to modify the **[insert name of document]** to address the deficiencies identified above pursuant to section **[insert section number]** of the **[insert Order/Decree]**. The modified **[insert name of document]** is enclosed. **[Insert name of company/group]** is required to implement the **[insert name of document]** as modified by EPA, subject only to its right to invoke dispute resolution procedures. **[For directed modifications, replace the previous two sentences with:** A list of modifications to the **[insert name of document]** is enclosed. **[Insert name of company/group]** is required to implement these EPA modifications, subject only to its right to invoke dispute resolution procedures. A revised **[insert name of document]** that implements these modifications must be submitted within **[insert days]** days of your receipt of this letter] **[RPM/Project Coordinator and/or ORC attorney should confirm that this**

paragraph is consistent with the provisions of the applicable enforcement instrument; UAOs typically do not contain dispute resolution procedures].

If you have any questions concerning this matter, please contact me at **[insert number]** or your legal counsel may contact **[insert name of EPA attorney]** at **[insert number]**.

Sincerely yours,

[Insert name of Project Coordinator]

Optional language to insert in place of paragraph 3 [at the Region's discretion if it decides to give the PRPs a second chance to respond to comments and resubmit the deliverable]:
If all comments are not adequately addressed, EPA may exercise its right to modify the document unilaterally and require implementation of the revised document. **[RPM/Project Coordinator and/or ORC attorney should confirm that this statement is consistent with the provisions of the applicable enforcement instrument. Consider also including the optional penalties language that is included in the sample letter for initial deliverables, which informs the PRPs that penalties will accrue until a satisfactory deliverable is received.]**

You are hereby requested to submit a response in writing to this office no later than **[insert number days]** days after receipt of this Notice of Deficiency that adequately addresses the above comments to establish compliance with the referenced **[insert Order/Decree]**.

For noncompliance with AOCs or CDs, optional language to insert after paragraph 2:
Please be advised that your resubmission of a deficient **[insert name of document]** constitutes a continuing violation of the **[insert Order/Consent Decree]** and that stipulated penalties began accruing on the day after a satisfactory version was initially due to be received by EPA. Consistent with the provisions of the **[insert Order/Consent Decree]**, stipulated penalties have continued to accrue until the date that EPA unilaterally prepared a satisfactory version of the **[insert name of document]**. **[For directed modifications, replace the previous sentence with:** Consistent with the provisions of the **[insert Order/Consent Decree]**, stipulated penalties will continue to accrue until the date that EPA receives a satisfactory version of the **[insert name of document]** from you that implements EPA's modifications.] **[The RPM/Project Coordinator and/or ORC attorney should confirm that this statement is consistent with the provisions of the applicable enforcement instrument. Some model instruments limit the number of days that stipulated penalties may accrue while EPA is reviewing a deliverable. Also, some model instruments link "material defects" in a deliverable to the assessment of stipulated penalties; the RPM/Project Coordinator and/or ORC attorney should consider modifying the letter to match that language as appropriate]**

For noncompliance with UAOs, optional language to insert after paragraph 2: Please be advised that EPA deems your resubmission of a deficient **[insert name of document]** to constitute a continuing violation of the UAO and, as a result, you may be subject to civil penalties of up to $37,500 for each day of this violation.

EXHIBIT 10

From: Wyatt, Robert [mailto:rjw@nwnatural.com]
Sent: Thursday, August 30, 2012 1:26 PM
To: Jennifer Woronets
Cc: Jim McKenna (Jim) (jim.mckenna@verdantllc.com); Patty Dost; LauraKennedy@KennedyJenks.com
Subject: FW: EPA incorporated resolutions to PH BHHRA

From: Kristine Koch [Koch.Kristine@epamail.epa.gov]
Sent: Thursday, August 30, 2012 1:22 PM
To: Wyatt, Robert
Subject: RE: EPA incorporated resolutions to PH BHHRA

Bob - please disregard Elizabeth's snarky comment on #57 in my email - I thought I scrubbed them all, but evidently not. Sorry.

Kristine Koch
Remedial Project Manager
USEPA, Office of Environmental Cleanup

U. S. Environmental Protection Agency
Region 10
1200 Sixth Avenue, Suite 900, M/S ECL-115
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From: "Wyatt, Robert" <rjw@nwnatural.com>
To: Kristine Koch/R10/USEPA/US@EPA
Cc: "jim.mckenna@verdantllc.com" <jim.mckenna@verdantllc.com>, "jworonets@anchorenv.com" <jworonets@anchorenv.com>, Cami Grandinetti/R10/USEPA/US@EPA, Lori Cora/R10/USEPA/US@EPA, Chip Humphrey/R10/USEPA/US@EPA, Elizabeth Allen/R10/USEPA/US@EPA, Sheila Fleming/R10/USEPA/US@EPA
Date: 08/30/2012 01:16 PM
Subject: RE: EPA incorporated resolutions to PH BHHRA

Thanks Kristine.

Bob

From: Kristine Koch [Koch.Kristine@epamail.epa.gov]
Sent: Thursday, August 30, 2012 1:07 PM
To: Wyatt, Robert
Cc: jim.mckenna@verdantllc.com; jworonets@anchorenv.com; Cami Grandinetti; Lori Cora; Chip Humphrey; Elizabeth Allen; Sheila Fleming
Subject: EPA incorporated resolutions to PH BHHRA

Bob - EPA believes that the discussions that we have had in the last two meetings were beneficial to

dispute resolution and have made the BHHRA a better document. EPA has made appropriate changes to the BHHRA based upon the agreements that were reached in the August 22 and 27 meetings. Some of the changes made by EPA may not be exactly as proposed and accepted due to language readability in the document, but EPA believes that the intent of the agreement was upheld. Please review the document to see if the LWG agrees. As agreed in the August 27th meeting, the LWG is to accept all changes made by EPA to the BHHRA that LWG agrees with, leaving those that LWG does not agree with as redline. The LWG is to further redline the document to include the specific issue resolutions that they are responsible for and provide to EPA next week. Note that we have identified a few more, below.

Specific modifications EPA made to resolutions are:

Table 1
5a - While this text was the LWG's original text, EPA noted that aldrin on results in a risk >1E-6 only in carp; aldrin was not a target analyte for bullhead and crappie.

Table 2
5 - EPA added some text to Section 3.2.1.8 noting that there are no known current uses of the LWR as a drinking water source. However, it turns out that for some reason household water use was never mentioned in the subsequent discussion of exposure pathways associated with surface water in Section 3.3.3, and EPA added domestic water use to that discussion.

8 - EPA modified language in this section.

13 - EPA deleted the existing sentence fragment that was at the beginning of the paragraph in Section 2.3.2, and deleted "generally" from the phrase that RSLs and MCLs were generally used as screening values. Otherwise, the language is correct and needs no further modification.

22 - Text regarding the purpose of the CT evaluations was added to the Section 3.4 discussion of exposure concentrations.

28 - The equation still needs to be fixed.

29 - A reference to Section 5.1.3 was added to Section 3.5.5

34 - Specific tribal consumption rates for salmon, lamprey, and sturgeon were added to Section 3.5.10.7.

37 - LWG needs to provide specific instances that are incorrect.

42 - EPA cleaned up the discussion in Section 5.2.6.3 a bit, and clarified that dioxins and furans were not analyzed for in fillet samples collected in Round 1.

44 - We agree that cPAHs aren't the primary contributors to the HI at RMs 5W and 6W, and revised Section 5.2.6.7 accordingly.

48 - EPA added text to Section 6.0 that states that EPA considers RME to represent the high end of the possible risk distribution, and that it is considered to be greater than the 90th percentile. The reference comes from the 1992 Habicht memo on Guidance for Risk Characterization for Risk Managers and Risk Assessors.

49 - LWG is to propose language, but Elizabeth's recommendation is to delete the section. The above-cited 1992 memo notes that "noteworthy" uncertainties are to be presented, defined as information that significantly influences the analysis. The conclusion at the end of Section 6.1.2 (and several others) that the specific uncertainties discussed don't really affect the conclusions seems to be at odds with the true intent of a presentation of uncertainties. However, EPA has made some edits to this sections and is willing to leave the discussion in the document if the LWG wants it.

52 - EPA previously added the requested reference to fillet samples in Section Section 6.1.10. EPA does not agree that deleting the reference to PCBs is appropriate, although it could be clarified to PCB TEQ. The discussion here is noting that both dioxins and dioxin-like PCB congeners typically contribute significantly to risk estimates in instances where the specific analyses were available. Hence, the reference to PCBs as well as dioxins here is appropriate.

57 - EPA revised the text in Section 6.2.5.5 to note that arsenic data from fish samples are reported as total arsenic, while EPA toxicity criteria are based on inorganic arsenic. The discussion is about the fudge-factor applied to convert total arsenic concentrations to inorganic concentrations. Given that the conclusions of this section are that none of it is a big deal, I think the revised text is fine and am not interested in further discussions regarding the number of angels that can dance on the head of a pin.

58 - LWG needs to provide text recommendation.

EPA made some revisions to Section 7. The LWG was already using the term COC there, when they claimed to have decided not to do so, and the resulting discussion was simply so confusing even the LWG couldn't keep track of terms. The whole point of the discussion is to define chemicals that potentially pose unacceptable risk, and the pathways associated with risks > $1x10^{-6}$ and HI > 1. EPA changed references to "primary contributors to risk," which was only a subjective term even in the LWG's use, and they are now are termed as contributing significantly to the risk estimates, to which EPA attaches no specific legal meaning. Same for primary contributors to risk, which now reside solely in Section 5.

Regards,

Kristine Koch
Remedial Project Manager
USEPA, Office of Environmental Cleanup

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EXHIBIT 11

POLICY ON CIVIL PENALTIES

EPA GENERAL ENFORCEMENT POLICY #GM - 21

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY

EFFECTIVE DATE: FEB 16 1984

Introduction

This document, Policy on Civil Penalties, establishes a single set of goals for penalty assessment in EPA administrative and judicial enforcement actions. These goals - deterrence, fair and equitable treatment of the regulated community, and swift resolution of environmental problems - are presented here in general terms. An outline of the general process for the assessment of penalties is contained in Attachment A.

A companion document, A Framework for Statute-Specific Approaches to Penalty Assessments, will also be issued today. This document provides guidance to the user of the policy on how to write penalty assessment guidance specific to the user's particular program. The first part of the Framework provides general guidance on developing program-specific guidance; the second part contains a detailed appendix which explains the basis for that guidance. Thus, the user need only refer to the appendix when he wants an explanation of the guidance in the first part of the Framework.

In order to achieve the above Agency policy goals, all administratively imposed penalties and settlements of civil penalty actions should, where possible, be consistent with the guidance contained in the Framework document. Deviations from the Framework's methodology, where merited, are authorized as long as the reasons for the deviations are documented. Documentation for deviations from the Framework in program-specific guidance should be located in that guidance. Documentation for deviations from the program-specific guidance in calculating individual penalties should be contained in both the case files and in any memoranda that accompany the settlements.

The Agency will make every effort to urge administrative law judges to impose penalties consistent with this policy and any medium-specific implementing guidance. For cases that go to court, the Agency will request the statutory maximum penalty in the filed complaint. And, as proceedings warrant, EPA will continue to pursue a penalty no less than that supported by the applicable program policy. Of course, all penalties must be consistent with applicable statutory provisions, based upon the number and duration of the violations at issue.

Applicability

This policy statement does not attempt to address the specific mechanisms for achieving the goals set out for penalty assessment. Nor does it prescribe a negotiation strategy to achieve the penalty target figures. Similarly, it does not address differences between statutes or between priorities of different programs. Accordingly, it cannot be used, by itself, as a basis for determining an appropriate penalty in a specific

action. Each EPA program office, in a joint effort with the Office of Enforcement and Compliance Monitoring, will revise existing policies, or write new policies as needed. These policies will guide the assessment of penalties under each statute in a manner consistent with this document and, to the extent reasonable, the accompanying Framework.

Until new program-specific policies are issued, the current penalty policies will remain in effect. Once new program-specific policies are issued, the Agency should calculate penalties as follows:

- For cases that are substantially settled, apply the old policy.

- For cases that will require further substantial negotiation, apply the new policy if that will not be too disruptive.

Because of the unique issues associated with civil penalties in certain types of cases, this policy does not apply to the following areas:

- CERCLA §107. This is an area in which Congress has directed a particular kind of response explicitly oriented toward recovering the cost of Government cleanup activity and natural resource damage.

- Clean Water Act §311(f) and (g). This also is cost recovery in nature. As in CERCLA §107 actions, the penalty assessment approach is inappropriate.

- Clean Air Act §120. Congress has set out in considerable detail the level of recovery under this section. It has been implemented with regulations which, as required by law, prescribe a non-exclusive remedy which focuses on recovery of the economic benefit of noncompliance. It should be noted, however, that this general penalty policy builds upon, and is consistent with the approach Congress took in that section.

Much of the rationale supporting this policy generally applies to non-profit institutions, including government entities. In applying this policy to such entities, EPA must exercise judgment case-by-case in deciding, for example, how to apply the economic benefit and ability to pay sanctions, if at all. Further guidance on the issue of seeking penalties against non-profit entities will be forthcoming.

Deterrence

The first goal of penalty assessment is to deter people from violating the law. Specifically, the penalty should persuade the violator to take precautions against falling into noncompliance again (specific deterrence) and dissuade others from violating the law (general deterrence). Successful deterrence is important because it provides the best protection for the environment. In addition, it reduces the resources necessary to administer the laws by addressing noncompliance before it occurs.

If a penalty is to achieve deterrence, both the violator and the general public must be convinced that the penalty places the violator in a worse position than those who have complied in a timely fashion. Neither the violator nor the general public is likely to believe this if the violator is able to retain an overall advantage from noncompliance. Moreover, allowing a violator to benefit from noncompliance punishes those who have complied by placing them at a competitive disadvantage. This creates a disincentive for compliance. For these reasons, it is Agency policy that penalties generally should, at a minimum, remove any significant economic benefits resulting from failure to comply with the law. This amount will be referred to as the "benefit component" of the penalty.

Where the penalty fails to remove the significant economic benefit, as defined by the program-specific guidance, the case development team must explain in the case file why it fails to do so. The case development team must then include this explanation in the memorandum accompanying each settlement for the signature of the Assistant Administrator of Enforcement and Compliance Monitoring, or the appropriate Regional official.

The removal of the economic benefit of noncompliance only places the violator in the same position as he would have been if compliance had been achieved on time. Both deterrence and fundamental fairness require that the penalty include an additional amount to ensure that the violator is economically worse off than if it had obeyed the law. This additional amount should reflect the seriousness of the violation. In doing so, the penalty will be perceived as fair. In addition the penalty's size will tend to deter other potential violators.

In some classes of cases, the normal gravity calculation may be insufficient to effect general deterrence. This could happen if, for example, there was extensive noncompliance with certain regulatory programs in specific areas of the United States. This would demonstrate that the normal penalty assessments had not been achieving general deterrence. In such cases, the case development team should consider increasing the gravity component sufficient to

achieve general deterrence. These extra assessments should balance the other goals of this policy, particularly equitable treatment of the regulated community.

This approach is consistent with the civil penalty provisions in the environmental laws. Almost all of them require consideration of the seriousness of the violation. This additional amount which reflects the seriousness of the violation is referred to as the "gravity component". The combination of the benefit and gravity components yields the "preliminary deterrence figure."

As explained later in this policy, the case development team will adjust this figure as appropriate. Nevertheless, EPA typically should seek to recover, at a minimum, a penalty which includes the benefit component plus some non-trivial gravity component. This is important because otherwise, regulated parties would have a general economic incentive to delay compliance until the Agency commenced an enforcement action. Once the Agency brought the action, the violator could then settle for a penalty less than their economic benefit of noncompliance. This incentive would directly undermine the goal of deterrence.

Fair and Equitable Treatment of the Regulated Community

The second goal of penalty assessment is the fair and equitable treatment of the regulated community. Fair and equitable treatment requires that the Agency's penalties must display both consistency and flexibility. The consistent application of a penalty policy is important because otherwise the resulting penalties might be seen as being arbitrarily assessed. Thus violators would be more inclined to litigate over those penalties. This would consume Agency resources and make swift resolution of environmental problems less likely.

But any system for calculating penalties must have enough flexibility to make adjustments to reflect legitimate differences between similar violations. Otherwise the policy might be viewed as unfair. Again, the result would be to undermine the goals of the Agency to achieve swift and equitable resolutions of environmental problems.

Methods for quantifying the benefit and gravity components are explained in the Framework guidance. These methods significantly further the goal of equitable treatment of violators. To begin with, the benefit component promotes equity by removing the unfair economic advantage which a violator may have gained over complying parties. Furthermore, because the benefit and gravity components are generated systematically, they

will exhibit relative consistency from case to case. Because the methodologies account for a wide range of relevant factors, the penalties generated will be responsive to legitimate differences between cases.

However, not all the possibly relevant differences between cases are accounted for in generating the preliminary deterrence amount. Accordingly, all preliminary deterrence amounts should be increased or mitigated for the following factors to account for differences between cases:

- Degree of willfulness and/or negligence
- History of noncompliance.
- Ability to pay.
- Degree of cooperation/noncooperation.
- Other unique factors specific to the violator or the case.

Mitigation based on these factors is appropriate to the extent the violator clearly demonstrates that it is entitled to mitigation.

The preliminary deterrence amount adjusted prior to the start of settlement negotiations yields the "initial penalty target figure". In administrative actions, this figure generally is the penalty assessed in the complaint. In judicial actions, EPA will use this figure as the first settlement goal. This settlement goal is an internal target and should not be revealed to the violator unless the case development team feels that it is appropriate. The initial penalty target may be further adjusted as negotiations proceed and additional information becomes available or as the original information is reassessed.

Swift Resolution of Environmental Problems

The third goal of penalty assessment is swift resolution of environmental problems. The Agency's primary mission is to protect the environment. As long as an environmental violation continues, precious natural resources, and possibly public health, are at risk. For this reason, swift correction of identified environmental problems must be an important goal of any enforcement action. In addition, swift compliance conserves Agency personnel and resources.

The Agency will pursue two basic approaches to promoting quick settlements which include swift resolution of environmental problems without undermining deterrence. Those two approaches are as follows:

1. Provide incentives to settle and institute prompt remedial action.

EPA policy will be to provide specific incentives to settle, including the following:

- The Agency will consider reducing the gravity component of the penalty for settlements in which the violator already has instituted expeditious remedies to the identified violations prior to the commencement of litigation.1/ This would be considered in the adjustment factor called degree of cooperation/noncooperation discussed above.

- The Agency will consider accepting additional environmental cleanup, and mitigating the penalty figures accordingly. But normally, the Agency will only accept this arrangement if agreed to in pre-litigation settlement.

Other incentives can be used, as long as they do not result in allowing the violator to retain a significant economic benefit.

2. Provide disincentives to delaying compliance.

The preliminary deterrence amount is based in part upon the expected duration of the violation. If that projected period of time is extended during the course of settlement negotiations due to the defendant's actions, the case development team should adjust that figure upward. The case development team should consider making this fact known to the violator early in the negotiation process. This will provide a strong disincentive to delay compliance.

1/ For the purposes of this document, litigation is deemed to begin:

- for administrative actions - when the respondent files a response to an administrative complaint or when the time to file expires or

- for judicial actions - when an Assistant United States Attorney files a complaint in court.

Intent of Policy and Information Requests for Penalty Calculations

The policies and procedures set out in this document and in the Framework for Statute-Specific Approaches to Penalty Assessment are intended solely for the guidance of government personnel. They are not intended and cannot be relied upon to create any rights, substantive or procedural, enforceable by any party in litigation with the United States. The Agency reserves the right to act at variance with these policies and procedures and to change them at any time without public notice. In addition, any penalty calculations under this policy made in anticipation of litigation are exempt from disclosure under the Freedom of Information Act. Nevertheless as a matter of public interest, the Agency may elect to release this information in some cases.

Courtney M. Price
Assistant Administrator for
Enforcement and Compliance Monitoring

Attachment

ATTACHMENT A

Outline of Civil Penalty Assessment

I. Calculate Preliminary Deterrence Amount

A. Economic benefit component and

B. Gravity component

(This yields the preliminary deterrence amount.)

II. Apply Adjustment Factors

A. Degree of cooperation/noncooperation (indicated through pre-settlement action.)

B. Degree of willfulness and/or negligence.

C. History of noncompliance.

D. Ability to pay (optional at this stage.)

E. Other unique factors (including strength of case, competing public policy concerns.)

(This yields the initial penalty target figure.)

III. Adjustments to Initial Penalty Target Figure After Negotiations Have Begun

A. Ability to pay (to the extent not considered in calculating initial penalty target.)

B. Reassess adjustments used in calculating initial penalty target. (Agency may want to reexamine evidence used as a basis for the penalty in the light of new information.)

C. Reassess preliminary deterrence amount to reflect continued periods of noncompliance not reflected in the original calculation.

D. Alternative payments agreed upon prior to the commencement of litigation.

(This yields the adjusted penalty target figure.)

EXHIBIT 12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 30, 1997

OFFICE OF
ENFORCEMENT AND COMPLIANCE ASSURANCE

MEMORANDUM

SUBJECT: Issuance of the Interim Policy on Settlement of CERCLA Section 106(b)(1) Penalty Claims and Section 107(c)(3) Punitive Damages Claims for Noncompliance with Administrative Orders

FROM: Steven A. Herman
Assistant Administrator

TO: Regional Administrators, Regions I-X
Regional Counsel, Regions I-X
Director, Office of Site Remediation and Restoration
Region I
Director, Emergency and Remedial Response Division
Region II
Director, Hazardous Waste Management Division
Regions III, IX
Director, Waste Management Division
Region IV
Director, Superfund Division
Regions V, VI, VII
Assistant Regional Administrator, Office of Ecosystems Protection and Remediation
Region VIII
Director, Environmental Cleanup Office
Region X

Attached is a policy for settling CERCLA §106(b)(1) civil penalty and §107(c)(3) punitive damages claims for noncompliance with administrative orders (AOs). Civil penalties may be sought when EPA enforces a §106(a) administrative order and punitive damages may be sought when Superfund monies have been spent as a result of noncompliance with an administrative order. The policy does not alter existing policy on the collection of stipulated penalties. The policy is issued in "interim" form to permit the Agency to gain greater experience with administrative order compliance issues.

Issuance of this policy is part of an ongoing effort to make the Superfund program fairer for the parties that take responsibility for cleaning up Superfund sites by taking appropriate enforcement action against those parties who are liable and who fail to participate in the cleanup. In the past, some have criticized EPA for failing to pursue noncompliers when private parties are conducting Superfund cleanups. The establishment of national guidelines for settling administrative order noncompliance cases should facilitate the government initiation and settlement of enforcement actions against noncompliers and produce consistent settlement results across the country. Although limited resources prevent EPA from initiating enforcement actions against every noncomplier, strategic targeting of enforcement actions against noncompliers is intended to deter noncompliance with administrative orders and encourage settlement of civil penalty and punitive damages claims when noncompliance occurs.

The policy is intended to make calculation of CERCLA civil penalties and punitive damages for purposes of settlement a fair and effective process for deterring noncompliance with EPA's administrative orders. The policy contains an innovative approach toward penalty calculation which takes into account factors particularly relevant to Superfund cases by incorporating both harm and equitable adjustment factors into a single "harm - recalcitrance" matrix. Unlike existing EPA penalty policies developed for the assessment of penalties in the Agency's regulatory programs, factors such as the noncomplier's degree of responsibility for the site and ability to finance compliance with an administrative order are considered early in the calculation process to encourage companies that have greater responsibility for the creation of the Superfund site and/or are better able to finance a cleanup to step forward and work with other viable PRPs to take responsibility for cleanups.

The policy provides for smaller penalties for noncompliance by smaller contributors to Superfund sites, companies with limited financial resources, and less sophisticated parties. This policy reserves the highest penalties for the most egregious offenders - the noncompliers who are financially capable of performing, who are most responsible for creating the Superfund site, and whose failure to perform results in actual harm to human health, the environment, or EPA's enforcement and response program, or results in serious inequities to complying parties.

Consistent with the Agency's "Policy on Civil Penalties" (Feb. 16, 1984), this policy should be used only in cases where the government is settling civil penalty and punitive damages claims. The government's decision to adjust a penalty based on case-specific factors for purposes of settlement reflects a determination that settlement of the case is in the government's interest. Where the government must litigate the case, the United States is free to seek substantially higher penalty and punitive damages amounts without being bound by the non-statutory mitigation factors outlined in this policy . This approach is consistent with the language and legislative history of CERCLA, which encourages settlement and disfavors noncompliance.

If you have any questions concerning the attached policy, please contact Steven Rollin, Policy and Guidance Branch, PPED, OSRE (202-564-5142).

cc: Sylvia Lowrance
Barry Breen
Eric Schaeffer
Linda Boornazian
Charles Breece
Lori Boughton
Earl Salo
Lead Region UAO Work Group
Bruce Gelber

Interim Policy on Settlement of CERCLA Section 106(b)(1) Penalty Claims and Section 107(c)(3) Punitive Damages Claims for Noncompliance with Administrative Orders

September 30, 1997

Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency

Contents

Interim Policy on Settlement of CERCLA Section 106(b)(1) Penalty Claims and Section 107(c)(3) Punitive Damages Claims for Noncompliance with Administrative Orders

I. Calculating Section 106(b)(1) Civil Penalties for Settlement

A. Overview of the Penalty Calculation Process

CERCLA §106(b)(1) establishes a maximum civil penalty of either $25,000 per day for noncompliance prior to January 30, 1997, or $27,500 per day for noncompliance on or after January 30, 1997 with a §106(a) administrative order (AO).[1] When settling a §106 penalty claim, this amount may be reduced according to the facts and circumstances of the noncompliance. Where more than one respondent fails to comply with a given AO, a penalty is calculated individually for each noncomplier - the penalty is not divided among noncompliers. Settlement of CERCLA §106(b)(1) penalty claims and Section 107(c)(3) punitive damages claims for failure to comply with administrative orders is generally in the form of judicial consent decrees.[2]

EPA's general regulatory civil penalty policies identify three criteria for determining an appropriate penalty amount: (1) the penalty should be large enough to serve as a deterrent, (2) it should treat the violator fairly and equitably, and (3) it should resolve swiftly the environmental problems posed by noncompliance, without compromising deterrence.[3] This policy provides a framework for determining an appropriate amount to accept in settlement of a claim for noncompliance with an AO. This policy does not specify particular settlement amounts for particular types of AO noncompliance because the consequences of noncompliance vary from

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[1]Section 106(b)(1) provides: "Any person who, without sufficient cause, willfully violates, or fails or refuses to comply with, any order of the President under subsection (a) may, in an action brought in the appropriate United States district court to enforce such order, be fined not more than $25,000 for each day in which such violation occurs or such failure to comply continues." Pursuant to EPA's Civil Monetary Penalty Inflation Adjustment Rule (implementing the Debt Collection Improvement Act of 1996), EPA adjusted for inflation the maximum civil monetary penalties that can be imposed pursuant to the Agency's statutes. For noncompliance with an administrative order that takes place after January 30, 1997, the maximum civil monetary penalty is $27,500 per day. Noncompliance with administrative orders that occurs prior to January 30, 1997 is subject to a maximum civil monetary penalty of $25,000.

[2]Settlement of penalty claims generally requires consultation with and approval of the Department of Justice.

[3] Two documents contain general civil penalty policies for Agency regulatory statutes: "Policy on Civil Penalties" (Feb. 16, 1984) and "A Framework for Statute-Specific Approaches to Penalty Assessments" (Feb. 16, 1984).

site to site.[4] The adverse effect of AO noncompliance may be only site-specific or also may include an impact on the Agency's enforcement program. This policy focuses on two areas of analysis: (1) the degree of harm caused by the noncompliance in light of the extent of deviation from the requirements of the AO and the impact of such deviation on site conditions, response activities, EPA's Superfund enforcement program, and other parties who have complied with or are complying with the AO or a consent decree; and (2) the degree of recalcitrance exhibited by the noncomplier in failing to comply with the AO, considering the noncomplier's degree of responsibility, financial and technical ability, past practices, and other relevant factors.

The policy outlines a three-step process for calculating a §106 penalty. First, a per day penalty should be determined by evaluating the harm caused by the noncompliance and the recalcitrance of the noncomplier. Second, the per day penalty should be multiplied by the number of days of noncompliance. If the noncomplier obtains an economic benefit by its noncompliance, that benefit should be calculated and added to the per day penalty, yielding the total penalty (which cannot exceed the statutory maximum). Finally, the total penalty may be adjusted by other factors, including litigation risk, the noncomplier's inability to pay a penalty, and the noncomplier's agreement to conduct a supplemental environmental project to arrive at an adjusted total penalty.

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[4] The process for calculating penalty amounts outlined in this policy deviates from " A Framework for Statute-Specific Approaches to Penalty Assessments: Implementing EPA's Policy on Civil Penalties" (Framework) (1984). The Framework process consists of selecting a "preliminary deterrence amount" which is the sum of economic benefit and the gravity component of a penalty. The preliminary deterrence amount is then adjusted by equitable factors, ability to pay, and litigation risk. In this policy, the factors which the Framework lists for selecting the gravity component and the equitable adjustment factors are incorporated into the definitions of the harm and recalcitrance classes which form the axes of the penalty matrix, the use of which produces the gravity component of the penalty. The factors discussed in the Framework are included in this policy but have not been broken out for line by line adjustment and no specific percentages for adjustments are included. The definitions of the harm and recalcitrance classes have been carefully drafted to ensure that use of this policy results in consistent and fair penalty calculations, as called for in the Framework. Further, the examples included in the policy provide sample calculations for many of the most common scenarios involving AO noncompliance.

Three -Step Process for Calculating Settlement Penalty

Step 1: Use Matrix to Select Per Day Penalty[5]

		Recalcitrance		
		Recalcitrance I	Recalcitrance II	Recalcitrance. III
Harm	Harm A	$17,600 to$27,500	$8800 to $17,600	$2750 to $8800
	Harm B	$8800 to $17,600	$2750 to $8800	$550 to $2750
	Harm C	$2750 to $8800	$550 to $2750	$110 to $550

Step 2: Calculate Total Penalty

(Per day Penalty x Period of Noncompliance) + Economic Benefit = Total Penalty

Step 3: Calculate Adjusted Total Penalty

Total Penalty - Final Adjustment Factors (Litigation Risk/SEPs/Ability to Pay) = Adjusted Total Penalty

Certain claims for enforcement of an AO may present unique factual or legal issues which fall outside the intended scope of these settlement penalty calculation guidelines. EPA

[5] Pursuant to EPA's Civil Monetary Penalty Inflation Adjustment Rule (implementing the Debt Collection Improvement Act of 1996), EPA adjusted for inflation the maximum civil monetary penalties that can be imposed pursuant to the Agency's statutes. For noncompliance with an administrative order that takes place after January 30, 1997, the maximum civil monetary penalty is $27,500 per day. Noncompliance with administrative orders that occurs prior to January 30, 1997 is subject to a maximum civil monetary penalty of $25,000. The matrix includes ranges based on a daily maximum civil monetary penalty of $27,500. Where noncompliance occurs before January 30, 1997, the enforcement team should ensure that the per day penalty does not exceed $25,000 per day.

may depart from the policy where its use produces inadequate or inappropriate results. The Ten Point Settlement Analysis[6] should document the bases for the departure.

B. Step 1: Selecting the Per Day Penalty

A per day penalty amount is calculated by determining the gravity of the administrative order noncompliance. The penalty matrix (see above) has nine cells, each containing a penalty range. The specific cell is chosen by classifying the noncompliance according to one of three levels of harm and one of three levels of recalcitrance which requires a careful analysis of the particular circumstances of the noncompliance and review of the harm and recalcitrance class definitions. The intersection of the harm and recalcitrance axes determines the range of penalty from which to identify an appropriate per day penalty. Enforcement teams[7] have discretion to select a specific penalty from within the range of penalty amounts for a particular harm and recalcitrance class combination based on a weighting of the factors listed for selecting the appropriate harm or recalcitrance class.

1. Selecting the Harm Category

a. Factors to be Considered in Selecting a Harm Classification

The harm category should reflect the threat to human health and the environment posed by conditions at a site[8], the impact of the noncompliance on the complying parties (and/or settlors) and on conditions at the site, and on the integrity of the enforcement program. Penalties for noncompliance should be higher when actual harm occurs as a result of the noncompliance. Higher penalties are also appropriate when site conditions pose an immediate threat to human health or the environment. Further, enforcement teams also may determine the harm category based upon the adverse impact on EPA's enforcement and response resources in circumstances where noncompliance requires EPA to take over a response action, diverting Superfund resources from other cleanups - including those cases where there may be no other viable parties to conduct the cleanup. Penalty category selection also should reflect the enforcement team's

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[6]The Ten Point Settlement Analysis is explained in EPA's 1984 Interim CERCLA Settlements Policy (50 Fed. Reg. 5034, Feb. 5, 1985); see also OSWER Directive 9835.14, Submittal of Ten Point Settlement Analyses of CERCLA Consent Decrees (August 11, 1989).

[7]Enforcement teams are generally composed of EPA enforcement personnel working on a Superfund case and, where applicable, Department of Justice (DOJ) staff. See EPA Enforcement Memorandum, Case Management Plans (March 11, 1988).

[8]The enforcement team may evaluate the threat using information found in the action memorandum for removal actions and RI/FSs, the risk assessment and/or the record of decision (ROD) for remedial actions, as well as other sources of information.

consideration of the extent to which compliers/settlors are burdened unfairly by the noncomplier's failure to coordinate and participate in the response action.

The following factors should be considered in determining the degree of harm and have been incorporated into the harm classification definitions:

- Degree of threat to human health or the environment (consider the quantity and toxicity of hazardous substances present at the site, the threat of explosion, fire or other release, the extent of migration or leaching, the existence, size, and proximity of human populations, including environmental justice considerations, and the existence of sensitive environmental media, the sensitivity of the environmental media, and the potential effects of ongoing exposure);

- Extent that failure to comply aggravates the threat to human health or the environment (consider whether there are or may be continued or additional releases of hazardous substances, the importance of the order to reducing risk or otherwise abating the release or threat of release, whether the noncompliance worsens conditions at the site to the extent that EPA and/or complying order recipients are unable to correct the effects of the noncompliance expeditiously, and whether additional media are or may be contaminated);

- Likelihood that the complying order recipients will complete the response action, including consideration of the compliers' financial resources;

- Impact on the integrity of EPA's enforcement program (consider the extent to which additional resources were diverted from other cleanups to address the noncompliance or to take over a response action and the effect of the noncompliance on the behavior of other parties at the site and other Superfund sites); and

- Increased burden on complying order recipients or settlors (consider whether the compliers/settlors have difficulty financing the work or obtaining the expertise to conduct the response action without the noncomplier)

b. <u>Defining the Harm Categories</u>

CLASS A: The noncompliance caused actual harm to human health or the environment at the site, resulted in continued or increased exposure or increased threat of explosion, or fire, caused other serious and immediate adverse consequences to human health or the environment from an actual release of hazardous substances, resulted in substantial burdens to EPA or settlors/complying order recipients, or a combination of the above.

CLASS B: The noncompliance resulted in an aggravated or significant threat to human health or the environment from a potential release of hazardous substances (This will usually occur when the quantity and toxicity is high, there is a large exposed population or the threat is imminent, but there is no immediate threat of fire or explosion or ongoing exposure) , resulted in significant burdens to EPA or settlors/complying order recipients, or a combination of the above.

CLASS C: The noncompliance occurred at a site where the toxicity of hazardous substances is not as high or the need for an accelerated cleanup is not as great, the noncompliance did not result in a significantly increased threat to human health or the environment from an actual or potential release of hazardous substances (which may occur when EPA or settlors/complying order recipients conduct the response action without delay), placed little or no burden on EPA or settlors/complying order recipients, or a combination of the above.

2. Selecting the Recalcitrance Category

a. Factors to be Considered in Selecting a Recalcitrance Classification

For purposes of this policy, "recalcitrance" focuses on aspects of the noncomplier's general circumstances and the noncomplier's site-specific behavior. Thus, the same type of noncompliance may fall into a higher or lower classification depending on factors which affect the noncomplier's behavior at the site, such as the noncomplier's degree of responsibility for the hazardous substances at the site, financial resources, and level of sophistication. While not excusing noncompliance, using these factors to distinguish among noncompliers serves the policy's goal of achieving both fairness and deterrence in the penalty calculation.

The recalcitrance class definitions are written so that higher penalties are appropriate for a noncomplier with even one negative factor, such as a history of recalcitrance. As a result, a noncomplier with a significant history of recalcitrance who refuses to comply with the order - total noncompliance - may fit within Recalcitrance Class I (assuming there are no significant mitigating factors). Thus, the Class I category would be particularly appropriate where the noncompliance is coupled with one or more aggravating factors. In contrast a noncomplier may have demonstrated a good faith effort to comply with the order for the site. To provide recognition (and a lower penalty) for the positive factor, the enforcement team should select a Class II or III penalty category. For example, the Class II category could be appropriate for instances of partial noncompliance with an AO. Even total noncompliance with an AO may result in a Class II determination if the noncompliance is coupled with an absence of aggravating factors or the presence of significant mitigating factors.

The following factors should be considered in selecting the appropriate recalcitrance category and have been incorporated into the recalcitrance classification definitions:

- o Extent of noncompliance;
- o Quality and timeliness of work performed;
- o Need for substantial oversight;
- o Noncomplier's degree of responsibility for the harm at the site (for example, volumetric share or other contribution to the release or threatened release of hazardous substances,[9] and degree of involvement in the selection of the site);
- o Degree of willfulness and/or negligence;[10]
- o History of recalcitrance at the site in question or a pattern of recalcitrance at Superfund sites generally; and

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[9]Enforcement teams may consider the noncomplying party's relative share of hazardous substances found at the site. This approach is intended to encourage the larger contributors of hazardous substances to the site, as well as owners and operators, to take greater responsibility for organizing PRP groups and for complying with AOs. For example, a generator PRP that contributes 50% of the hazardous substances to the site and then refuses to comply with an order should pay a larger penalty than the party that fails to comply but is responsible for a smaller share.

[10]Although willfulness is not a statutory prerequisite for enforcement of an administrative order, a higher penalty may be appropriate for a willful violation. In determining whether a violation is willful, each of the following factors should be considered with respect to the noncomplier's behavior in refusing to comply with the AO (how the noncomplier became involved with the Superfund site is not relevant):

- o Extent of respondent's control over events constituting the violation;
- o Foreseeability of events constituting the violation;
- o Whether reasonable precautions were taken by respondent to avoid the events constituting the violation;
- o Whether respondent knew or should have known of hazards associated with its conduct; and
- o the level of sophistication within the industry in dealing with compliance issues.

- Good faith attempts to comply (may take into consideration noncomplier's ability to finance the work required by the order,[11] sophistication of noncomplier, and attempts to participate and coordinate with complying respondents)[12]

b. Defining the Recalcitrance Categories

CLASS I: The noncompliance consists of total noncompliance or such poor work as to be tantamount to total noncompliance, where there is evidence of significant bad faith, a history of recalcitrance, a willful violation, responsibility for a large share of the response costs, or other evidence of significant recalcitrance.

CLASS II: The noncompliance consists of partial noncompliance, work of poor quality, work deficiencies requiring significant oversight, and/or a pattern of delayed compliance. Total noncompliance may also be Class II recalcitrance where there is evidence that the noncomplier made a sufficient good faith effort to comply with the order, has no history of recalcitrance, there is no evidence of a willful violation, is not responsible for a large share of the response costs, or there are other mitigating factors suggesting a lower degree of recalcitrance.

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[11]Enforcement teams may consider the noncomplying party's financial resources and its ability to fund and/or contribute to the cleanup. The penalty should be appropriate in light of these resources while being of sufficient magnitude to deter noncompliance. Similarly, although compliance is not excused for an order recipient with limited finances, the penalty may reflect its greater difficulty in financing response work. Enforcement teams have the discretion not to seek a penalty for a party with limited financial resources who fails to comply with an order because of unreasonable demands from other parties.

[12]Good faith efforts to comply include prompt identification and reporting of anticipated noncompliance, and prompt institution of measures to remedy the noncompliance. Any beneficial change in management personnel or policies following AO noncompliance may be considered by the enforcement team as evidence of a good faith effort. Downward penalty adjustment may be appropriate if new management practices demonstrably foster increased AO compliance.

Early notification of difficulty complying with order terms may also justify a change in class of recalcitrance or a reduction within the range of the penalty for a particular class of recalcitrance. Notification increases the potential for speedy resolution of compliance difficulties. Notice of anticipated inability to comply, however, without attempts to implement measures to correct or prevent recurrence of noncompliance, may not represent good faith efforts to comply.

CLASS III: Class III noncompliance includes missed interim deadlines on primary tasks where the work performed meets specifications and/or inadequate completion of a task ancillary to the primary work requirements. Failure to comply with reporting requirements, such as failure to submit a monthly report, may also be Class III noncompliance. Partial compliance, work of poor quality, work deficiencies requiring significant oversight, and/or a pattern of delayed compliance may also be Class III recalcitrance where there is evidence that the noncomplier made a sufficient good faith effort to comply with the order, has no history of recalcitrance, there is no evidence of a willful violation, is not responsible for a large share of the response costs, or there are other mitigating factors suggesting a lower degree of recalcitrance.

3. Further Guidance on Selecting a Penalty from the Range Provided by the Harm/Recalcitrance Classification

After selecting the appropriate harm/recalcitrance classification, enforcement teams have discretion to select a specific penalty from within the penalty range provided by the matrix. The mid-range penalty is the starting point for determining the most appropriate per day penalty. However, the factors set forth above to be considered in assessing the degree of harm or recalcitrance should be balanced against any mitigating or aggravating considerations to determine whether a penalty in the higher or lower end of the range may be appropriate. In addition, the recalcitrance classes are defined to provide that one or more negative recalcitrance factors suggest a higher penalty class. To distinguish noncompliers with more than one negative factor or with one or more positive factors, enforcement teams can move within the penalty range based on a weighting of the factors listed for selecting the appropriate harm or recalcitrance class. Movement within in a penalty range provides the enforcement teams with the flexibility needed to select appropriate penalties and distinguish among noncompliers.

4. Examples[13]

Each example includes a description of the noncomplier followed by several scenarios describing the actions of other parties and the condition of the site. These examples are intended to clarify the use of the matrix by suggesting appropriate penalty categories based on a combination of factors involving the noncomplier, other parties involved at the site, and the condition of the site. The result listed is the suggested penalty for the noncomplier described in the example.

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[13]Results are middle of the range for each harm/recalcitrance category unless otherwise noted.

Example 1: A financially sound and sophisticated company responsible for the highest share (considering both volume and toxicity) of hazardous substances at the site refuses to comply with a UAO as it has at several sites.

Scenario 1 - A second financially sound and sophisticated company responsible for a high share (considering both volume and toxicity) of hazardous substances at the site performs completely without delay. RESULT: CLASS C-I.

Scenario 2 - Another party struggles to finance the cleanup without the participation of the noncomplier and has completed the remedial design without missing any deadlines. RESULT: CLASS A-I (unclear whether complier will be able to complete the response action).

Scenario 3 - EPA performs completely without delay. RESULT: CLASS B-I

Scenario 4 - Another party tries to perform but creates a threat of explosion at the site and EPA takes over its tasks. RESULT: High end of CLASS A-I.

Scenario 5 - EPA performs completely but cleanup is delayed during attempts to attain compliance, resulting in a continued imminent threat of a potential release into the nearby community. RESULT: High end of CLASS B-I.

Example 2: A financially sound and sophisticated company responsible for a small, but not de minimis share (considering both volume and toxicity) of hazardous substances at the site with no prior Superfund experience fails to comply

Scenario 1 - A second financially sound and sophisticated company responsible for a high share (considering both volume and toxicity) of hazardous substances at the site performs completely without delay. RESULT: CLASS C-II

Scenario 2 - Another party struggles to finance the cleanup without the participation of the noncomplier and has completed the remedial design without missing any deadlines. RESULT: High end of CLASS B-II (unclear whether complier will be able to complete the response action)

Scenario 3 - EPA performs completely without delay. RESULT: High end of CLASS C-II

Scenario 4 - Another party tries to perform but creates a threat of explosion at the site and EPA takes over its tasks. RESULT: High end of CLASS A-II.

Scenario 5 - EPA performs completely but cleanup is delayed during attempts to attain compliance, resulting in a continued imminent threat of a potential release into the nearby community. RESULT: High end of CLASS B-II.

Example 3: Sophisticated, financially sound company is the only complier of five order recipients. After completing the design phase of the remedial action, the company refused to continue compliance.

Scenario 1 - A second financially sound and sophisticated company, newly identified as a PRP, completes the response action without further delay after receiving a UAO ordering completion of the remainder of the response action. RESULT: CLASS C-II.

Scenario 2 - After a newly identified, second financially sound and sophisticated company complies with the UAO, the noncomplier agrees to resume compliance. Result: CLASS C-III.

Scenario 3 - A group of newly identified PRPs, each with limited finances, struggles to complete the remedial action (in accordance with a second round UAO) without the participation of the noncomplier and as of the date of settlement negotiations has not missed any deadlines. RESULT: High end of CLASS B-II (unclear whether compliers will be able to complete the response action)

Scenario 4 - EPA performs completely without delay. RESULT: CLASS B -II

Scenario 5 - A newly identified PRP tries to perform but creates a threat of explosion at the site and EPA takes over its tasks. RESULT: High end of CLASS A-II.

Scenario 6 - EPA performs completely but cleanup is delayed during attempts to attain compliance, resulting in a continued imminent threat from a potential release to the nearby community. RESULT: High end of CLASS B-II.

Example 4: An unsophisticated and financially limited party ordered to provide site security and maintain the groundwater pump and treatment system fails to comply.

Scenario 1 - A financially sound and sophisticated company responsible for a high share (considering both volume and toxicity) at the site performs completely without delay. RESULT: CLASS C-III

Scenario 2 - EPA performs completely without delay. RESULT: CLASS B-III

Scenario 3 - Another party conducting response action at the site creates a threat of explosion at the site (aggravation of harm not related to performance of the

noncomplier's tasks) and EPA takes over its tasks, including the noncomplier's ancillary tasks. RESULT: High end of CLASS C-III

Scenario 4 - Local vandals smash drums at the site, resulting in the release of hazardous substances into a nearby stream (and causing severe chemical burns and eye damage to the vandals) and creating a threat of explosion at the site from the combination of hazardous substances. EPA takes over performance of security for the site. RESULT: High end of CLASS A-III.

Scenario 5 - EPA takes over security functions at the site after discovering that trespassers riding motorcycles have created ruts in the cap, leading to erosion of the cap and resulting in a continued imminent threat from a potential release to a nearby community. RESULT: High end of CLASS B-III.

Example 5: Following entry of a consent decree providing for a group of PRPs to conduct the response action at an urban site with nearby residences, EPA issues a "coordinate and participate" order to a sophisticated and financially sound nonsettlor who is a major contributor to the site. The nonsettlor fails to comply with the order.

Scenario 1 - The settlors, responsible for 50% of the hazardous substances at the site, perform completely without delay. RESULT: CLASS C-I

Scenario 2 - The settlors struggle to finance the cleanup without the participation of the noncomplier and have completed the remedial design without missing any deadlines. RESULT: CLASS A-I (unclear whether settlors will be able to complete the response action).

Scenario 3 - The settlors try to perform but create a threat of explosion at the site and EPA takes over the response action. RESULT: High end of CLASS A-I.

Scenario 4 - After the settlors run out of money, EPA performs completely but cleanup is delayed during attempts to attain compliance, resulting in a continued imminent threat of a potential release into the nearby community. RESULT: High end of CLASS B-I.

C. Step 2: Determining the Total Penalty

The per day penalty amount established by application of the matrix should be multiplied by the number of days of noncompliance. Next, economic benefit, if any, is added to ensure that noncompliers do not save money by failing to comply.

1. Period of Noncompliance

This section provides general policy on the determination of the number of days to be included in the period of noncompliance. To the extent that the terms of the order specify when noncompliance occurs, the order, and not this policy, controls the determination of the period of noncompliance.

a. Failure to Initiate Work and Work Stoppage

If there are no complying order recipients, the period of noncompliance should begin on the day following the first missed milestone (which may be the date specified in the order for informing EPA that it will comply with the order) or work deadline. If all order recipients stop work, the period of noncompliance should run from the last day that site work was done or from the day following the deadline for the first missed deliverable for non-field activities, such as design work.

The noncompliance period should end (a) when the noncomplier demonstrates compliance with the order,[14] (b) when the work required by the original order is completed by other order recipients or pursuant to a subsequent order or consent decree, or (c) when EPA initiates the work required by the order.[15] The precise point when EPA "takes over" site work varies by site condition, type of noncompliance, and what is required to "take over" the work. The official date may be fixed when EPA makes its decision to perform, or commits Fund resources to perform site response work.[16]

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[14]If other parties are not completing the work, the noncomplier may demonstrate compliance with the order by meeting the first milestone or work deadline. If other parties are conducting the response action, the noncomplier may demonstrate compliance by working with the compliers. The required performance may include payment of money or performance of work as agreed to by the complying PRPs.

[15]For purposes of this settlement policy only, the ending dates for the period of noncompliance differ depending on whether a complying PRP (or group of complying PRPs) or EPA is conducting the work because the noncomplier can choose to work with the complying PRPs at any time prior to completion of the response action. However, for purposes of settlement only, this policy suggests that the period of noncompliance for calculation of penalties ends when EPA takes over the work, at which point EPA begins calculating punitive damages.

[16]The most appropriate end date generally is when EPA notifies respondent that its authority has been terminated or when EPA commits resources to take over site work. AOC terms, e.g., for dispute resolution, also may govern the date.

b. One or More Order Recipients Drop Out of Compliance

When one or more order recipients drops out of the complying group and the group continues to perform the response action, EPA will determine the period of noncompliance with the order. Typically, such noncompliance begins on the day following the date that the noncomplier fails to meet the performance requirement contained in the complying group's internal agreement or the date of the noncomplier's withdrawal from the group, whichever is earlier.[17] If the noncomplier had agreed to pay money, then the period of noncompliance begins on the date of the missed payment. If the noncomplier had agreed to perform work, then the period of noncompliance begins on the missed deadline for performance of the work.

The period of noncompliance ends (a) when the order recipient resumes compliance with the order, (b) when the work required by the order is completed by other order recipients/settlors or (c) if the remaining order recipients/settlors fail to complete the work, when EPA initiates the work required by the order.

c. Single vs. Multiple Violations

When a deadline is missed for an AO deliverable or for response work completion, the period of noncompliance should begin the day following the missed deadline. Administrative orders, including such items as work plan requirements and deadlines, may contain a series of related deadlines. Missed deadlines generally are treated as separate acts of noncompliance, and penalties are calculated for each act. For purposes of settlement only, missed interrelated deadlines, however, may comprise only one act of noncompliance, and only a single penalty may be appropriate. For example, missing both the interim deadline for submitting a draft feasibility study (FS) and the final deadline for submitting a completed FS generally should be considered one act of noncompliance. The enforcement team should calculate the period of noncompliance beginning with the first missed deadline and ending with completion of the work or submission of the deliverable subject to the last missed deadline.

Where work tasks are not closely related, a penalty may be calculated for each. For example, a removal action may require the installation of a fence around the property to provide site security as well as the removal of drummed waste at the site as initial steps. The two discrete tasks, the installation of the fence and the removal of the drums, can be performed independently, and a failure to do either may be considered a separate act of noncompliance. The enforcement team should keep in mind that the statute provides for a maximum per day penalty even if there are multiple actions that constitute noncompliance occurring on the same day. Thus, if the

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[17] The remaining members of the complying group may provide the government with the noncomplier's notice of withdrawal from the group or a letter to the noncomplier documenting its failure to perform as required by their internal agreement.

fencing and drum removal are required to be done on the same day, but are not, then $27,500[18] is the highest possible total penalty.

d. Inadequate Work

The period of noncompliance for work that is inadequately performed, such as deficient plans, should be calculated from the date the work is due under the order. The penalty period should end once the deficient work has been corrected.

2. Calculate and Add Economic Benefit

Enforcement teams should ensure that the penalty captures the economic benefit of noncompliance, if any. At least initially, noncompliers benefit from noncompliance with an AO by avoiding response costs. If the complying parties/settlors successfully sue for contribution, the noncomplier will be required to pay its share of response costs, plus interest. The payment required by the contribution action, plus reimbursement of EPA's enforcement costs and punitive damages likely will recover this economic benefit. Similarly, if EPA undertakes the work and then recovers its costs plus interest from the noncomplier, the settlement or judgment amount will recover economic benefit. In contrast, if the noncomplier delays the implementation of costly response work for a significant amount of time prior to completing the work, the noncomplier will benefit from the use of its money during the period of delay.

When the enforcement team suspects that the noncomplier has benefitted from noncompliance and will continue to do so, it should calculate the economic benefit of noncompliance using the BEN computer model. For purposes of this settlement policy and notwithstanding each noncomplier's joint and several liability for an AO issued to a group, the enforcement team should apportion economic benefit among the financially viable noncompliers based on their estimated share of the cost of the response work ordered rather than the entire amount of the cost estimate for the work ordered where allocation information is available. Where the noncomplier signed an agreement with settling or complying parties which documents its promised contribution, the economic benefit may be calculated based on this commitment. Economic benefit of noncompliance is added to the calculated penalty to yield a total penalty.

D. Step 3: Final Reductions

After an appropriate penalty amount has been calculated, the enforcement team may determine that final reductions to this amount are warranted based upon litigation risk, the noncomplier's inability to pay, or the use of Supplemental Environmental Projects. The applicability of these final reduction considerations may not become known to the enforcement

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[18]The maximum total penalty for noncompliance with an administrative order prior to January 30, 1997 is $25,000 per day. See footnote 5, above, for further explanation.

team until after a demand for civil penalties has been made. For example, information in support of a noncomplier's claim of inability to pay the civil penalty amount likely will not be proffered until after a demand for the penalty has been made. Accordingly, the three final reduction factors discussed below may be used to reduce a penalty amount at any point in the settlement process. However, the basis for reduction must be fully explained in the Ten Point Settlement Analysis and reflected in the final penalty worksheet. The enforcement team may determine that unusual site-specific circumstances justify a departure from the numbers derived by application of this policy. In that event, the rationale for the proposed settlement shall be set forth in the Ten-Point Settlement Analysis.

1. Litigation Risk

Penalty reduction based on the strength of the government's case or respondent's defenses should reflect the specific strengths and weaknesses of the enforcement action. The enforcement team should evaluate the strength of the liability case, the strength of any sufficient cause defense(s), potential challenges to the selected response action, the adequacy of the administrative record supporting the response action, the clarity of the order, and judicial precedent. Evaluation of these factors is within the discretion of the enforcement team in consultation with the team members' supervisors.

There may be instances where the penalty calculated using the full period of noncompliance is disproportionate to the gravity of the noncompliance or the total site response costs. In instances where the enforcement team concludes that the duration of the violation yields a disproportionately high penalty, the enforcement team may recommend that the penalty be reduced for purposes of calculating the final penalty amount[19]

Penalty reductions due to litigation risk should be documented in the Ten Point Settlement Analysis and penalty worksheet as described further in Section IV of this policy. Reductions should be broken out for the gravity portion of the penalty, the economic benefit portion of the penalty, and punitive damages if the strength of the litigation case differs for each type of claim.

2. Inability to Pay

The penalty may be adjusted to take into account the noncomplier's inability to pay the calculated total civil penalty. If the noncomplier demonstrates an inability to pay the penalty, EPA may consider installment payments or delayed payment with interest. If the noncomplier demonstrates an inability to pay the full amount of the penalty, even over a longer term, then the

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[19]EPA's Office of Enforcement and Compliance Assurance (OECA) is available to provide consultation to enforcement teams to provide national consistency. To that end, OECA has data on penalties entered.

enforcement team has discretion to reduce the penalty. Decisions made to adjust the term or penalty amount are based on an evaluation of the noncomplier's financial condition.[20] Although the penalty may reflect the noncomplier's financial condition, it still should retain an adequate deterrent effect.

It is the noncomplier's burden to demonstrate its inability to pay the full amount of the penalty. The enforcement team should consider all resources available to the noncomplier claiming an inability to pay a penalty.[21] Useful financial information may be obtained through tax returns, audited financial statements, loan applications, financing and security agreements, annual reports to shareholders, SEC filings, Dun & Bradstreet reports, and similar financial reporting services. In addition, the enforcement team should consider whether payment of the penalty would jeopardize further site response activities.

3. Supplemental Environmental Projects

To further EPA's goals to protect and enhance public health and the environment, the Agency encourages the use of Supplemental Environmental Projects (SEPs) in settlements provided the requirements of the SEP guidance are satisfied. See "Interim EPA Supplemental Environmental Projects Policy" (May 3, 1995). Supplemental environmental projects are defined as environmentally beneficial projects which a noncomplier agrees to undertake in settlement of an enforcement action, but which the violator is not otherwise legally required to perform. The adjustment for a SEP, if any, is the final step in determining the appropriate penalty amount.

II. Calculating Section 107(c)(3) Punitive Damages for Settlement

A. Relationship Between Civil Penalties and Punitive Damages

CERCLA §107(c)(3) punitive damages may be appropriate whenever noncompliance with an administrative order causes EPA to expend money from the Fund.[22] Noncompliance that

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[20] See generally, Guidance on Determining a Violator's Ability to Pay a Civil Penalty (Dec. 16, 1986); General Policy on Superfund Ability to Pay Determinations (Sept. 30, 1997).

[21] Resources include cash on hand; salable assets; ability to borrow funds (increase respondent's debt); ability to sell stock (decrease respondent's equity); forgoing or deferring planned expansion investments and other planned expenditures; and in some cases, ability to obtain insurance payments. Internal expenditures, such as executive salaries, entertainment funds, and car rentals, should also be considered in evaluating ability to pay.

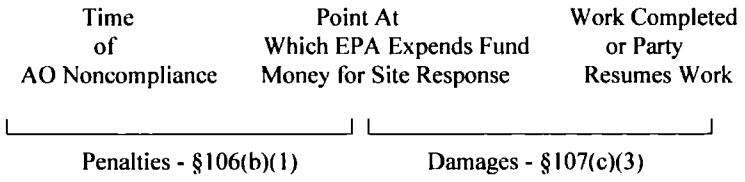
[22] Section 107(c)(3) provides: "If any person who is liable for a release or threat of release of a hazardous substance fails without sufficient cause to provide removal or remedial action upon order of the President pursuant to section 104 or 106 of this Act, such person may be liable to the United States for punitive damages in an amount at least equal to, and not more than three times, the amount at least equal to, and not more than three times, the amount of costs incurred by the Fund as a result of such failure to take proper action. The President is authorized to commence a civil action against any such person to recover the punitive damages which shall be in addition to any costs recovered

results in the expenditure of Fund money to perform site work required by the AO, or resulting in additional enforcement costs is serious because it requires substantial diversion of Agency resources from other sites.

1. Noncompliance Resulting in EPA Site Work

Congress included CERCLA section 107(c)(3) as an indication that administrative order noncompliance requiring EPA to perform some or all response activities warrants punitive damages commensurate with the noncompliance. Punitive damages under §107(c)(3) work in tandem with §106(b)(1) penalties. For settlement purposes only, when respondent's noncompliance results in EPA incurring response costs, EPA may consider calculating §106(b)(1) penalties based on a period of noncompliance ending at the time spends fund money to perform the response work.

The relationship between the accrual of civil penalties and punitive damages suggested as an approach by this policy is represented graphically below.



2. Noncompliance Resulting in Enforcement Costs

Administrative order noncompliance often results in Fund expenditures for enforcement costs, even if EPA does not take over site response work. For example, the noncompliance may result in EPA taking any or all of the following enforcement actions: to compel compliance, to recover civil penalties and punitive damages, and to have other parties take over site response work pursuant to a new or revised AO. When AO noncompliance requires Fund expenditures before EPA takes over site work, EPA may assert a punitive damages claim for these enforcement costs.

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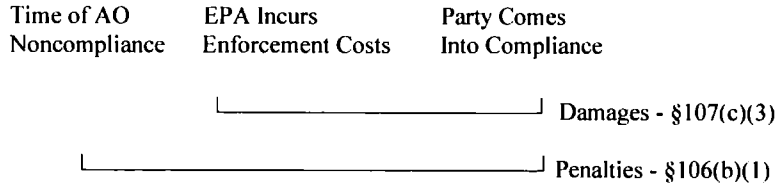
from such person pursuant to section 112(c) of this Act. Any moneys received by the United States pursuant to this subsection shall be deposited in the Fund."

The suggested approach to calculating penalties and enforcement cost damages is presented graphically in the example below.

Party violates administrative order; EPA initiates enforcement efforts, eventually resulting in party coming into compliance.



B. Calculating Punitive Damages Claims

EPA needs to maintain a strong enforcement program and send strong messages that PRPs are expected to comply with Administrative Orders to conduct response actions. Where parties do not comply, EPA must use funds that could have been used for other cleanups. Recovery of punitive damages is generally appropriate in cases where PRPs are not complying with the Administrative Order and EPA incurs response costs. Punitive damages are calculated at up to three times Fund expenditures in addition to recovery of costs incurred by EPA in site enforcement and response actions.[23] Where the AO is issued to a group of noncompliers, §107 punitive damages are calculated against each noncomplier for up to the full amount of three times the government's costs and are not divided among the group of noncompliers.

In calculating the amount of the punitive damages claim, enforcement teams should begin with the presumption that they will seek the full measure of punitive damages. In instances where seeking the full measure of punitive damages would be inconsistent with the goal of obtaining an equitable settlement of the specific violation, the enforcement team may recommend a compromise of punitive damages. Any recommendation to compromise punitive damages must be weighed against the need to maintain a strong deterrent to AO violations, particularly in cases where the violation results in the diversion of substantial Superfund resources from cleanups at other sites. Reductions in the punitive damages claim should consider factors comparable to the "harm" and "recalcitrance" criteria discussed in connection with the compromise of civil penalties. Other adjustments may include reductions for litigation risk and ability to pay. An additional relevant factor may be a non-compliers ability and committment to perform a SEP.

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[23]See United States v. Parsons, 936 F.2d 526 (11th Cir. 1991) (awarded costs plus treble damages); United States v. Lecarreaux, 1992 U.S. Dist. LEXIS 9365 (D.N.J. Feb. 18, 1992) (same).

III. Provisions for Stipulated Penalties in Orders on Consent

Administrative orders on consent (AOCs) include stipulated penalties for noncompliance with AOC provisions. AOCs generally reserve the government's right to seek statutory penalties even for violations covered by stipulated penalties. If stipulated penalties fail to deter noncompliance or if EPA otherwise believes that the stipulated penalties are inadequate to address the violation, it is appropriate to invoke any reserved statutory penalty authority.

IV. Documentation of Penalty and Damages Claims

A. Pre-negotiation Penalty and Punitive Damages Calculations

The penalty and/or punitive damages amounts should be clearly documented in a worksheet format. See Appendix A for a sample worksheet. The worksheet should be filed in the primary case file (generally a central file room or the Office of Regional Counsel if there is no central file room). The worksheet should also be attached to the Ten Point Settlement Analysis. These documents are enforcement sensitive work products and will not generally be made available to PRPs and the public.

Justifications for penalty and damages calculations, including adjustments, should be clearly explained with references to the circumstances of the specific site. Information from CERCLA §104(e) information requests, or affidavits from responsible parties or others may be used to justify adjustments to penalties. In negotiating a reduction with the Agency, the burden is on the AO violator to prove that a reduction is justified and to provide sufficient documentation as requested by the enforcement team.

B. Deviation From This Policy and Headquarters Consultation Requirements

If an enforcement team determines that a particular case requires deviation from this policy, this decision should be documented clearly in the Ten Point Settlement Analysis and the justification for developing the alternate penalty or damages claim should be clearly stated. At this time, Headquarters consultation is required for settlements less than 100 percent of a treble damages claim or less than 50% of the106(b) civil penalty calculated in accordance with this policy. Headquarters concurrence is required as well for settlements which significantly deviate from written Agency policy. The enforcement team should consult current delegation memoranda and complete consultation requirements prior to finalizing a settlement.

C. Final Settlement Amount

Once initial settlement amounts have been determined for all §106 penalty and §107 punitive damages claims, it may be appropriate to settle the multiple claims by a single amount. Enforcement teams may negotiate each claim separately and aggregate them in a single settlement amount or may negotiate a single amount that represents settlement of multiple

claims. The settlement document, however, should break out the cost recovery claim and the penalty and damages claims. The breakout may also affect whether the settlement payment is deductible for tax purposes and whether insurers will reimburse the settlers. The enforcement team should consider these issues in finalizing the settlement document.

The Ten Point Settlement Analysis and penalty worksheet (internal government settlement documents) should also break out the settlement amount into the cost recovery claim, penalty claim, and punitive damages claim for internal accounting purposes. The enforcement team has the discretion to determine the breakout although the penalty should not exceed the $27,500 per day of noncompliance [24] or treble the amount of Fund costs expended.

The settlement document may specify that payment of the specified amount is in satisfaction of all §106 and §107 claims. The United States may covenant not to sue or to take administrative action against the settling party upon payment, only for the administrative order noncompliance underlying the §106 and/or §107 claims.

V. Purpose and Use of This Policy

NOTICE: The policies set out in this memorandum are not final agency action, but are intended solely as policy. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the policy provided in this memorandum, or to act at variance with the policy, based on an analysis of specific site circumstances. The Agency also reserves the right to change this policy at any time without public notice.

If you have any questions concerning the attached policy, please contact Steven Rollin, Program Policy and Guidance Branch, PPED, OSRE (202-564-5142).

Additional copies of this document can be ordered from the National Technical Information Service (NTIS), U.S. department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Each order must reference the NTIS item number, PB97-208086. For telephone orders or further information on placing an order, call NTIS at (703) 487-4650 or (800) 553-NTIS. For orders via E-mail/Internet, send to the following address: orders@ntis.fedworld.gov.

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[24]The maximum total penalty for noncompliance with an administrative order prior to January 30, 1997 is $25,000 per day. See footnote 5, above, for further explanation.

APPENDIX A: SAMPLE WORKSHEET FOR DOCUMENTATION OF PENALTY AND TREBLE DAMAGES CLAIMS

Site Name and Location:

Case Name:

Enforcement Team Members and Phone Numbers:

I. PENALTY CLAIM: TOTAL PENALTY $_____

Step 1: Per Day Penalty

List harm classification _____ and list recalcitrance classification _____. List dollar amount of penalty selected from appropriate cell in matrix $_____.

justification for harm classification (review factors and definitions found in Section I.B.1)

Describe harm or threat of harm:

justification for choice of penalty within range of harm classification box:

Describe burden to EPA:

Describe burden on Complying PRPs/Settlors

justification for recalcitrance classification (review factors and definitions found in Section I.B.2)

Describe degree of noncompliance (total, poor work and type of work involved, work deficiency requiring significant oversight, partial, missed deadlines and type of task missed, and/or noncompliance with a reporting requirement)

Step 2: Total Penalty

i. Period of Noncompliance is _____ (date) to _____ (date) for a total of _____ days OR consider 180 Day Cutoff where appropriate (see Section I.C.1.e.). Period selected is _____.

justification:

ii. Per Day Penalty (Step 1) $_____ x period of noncompliance _____ = calculated total penalty of $_____.

iii. Add economic benefit of noncompliance $_____

attach BEN computer model printout (or explain why BEN was not necessary to determine that noncomplier did not benefit economically from noncompliance):

iv. Calculated total penalty (Step 2, ii) $_____ + economic benefit of noncompliance (Step 2, iii) $_____ = Total Penalty $_____.

II. Punitive Damages Claim = $_____.

Step 1: Initial Punitive Damages Claim

Amount of Site Response Costs, including enforcement costs resulting from AO violation $_____ + 3 x $_____ = $_____.

Step 2: Punitive Damages Claim Adjusted for Gravity

Reduction based on factors comparable to "harm" and "recalcitrance" factors = $_____.
Other adjustments = $_____.

III. Settlement Amount Adjusted for Litigation Risk and Ability to Pay = $-_____.

Step 1: Litigation Risk Reduction

Litigation Risk Reduction if any: $_____. It may be necessary to break out the litigation risk reduction to the gravity portion of the penalty claim $_____, the economic benefit portion of the penalty claim $_____, and the damages claim $_____ if the strength of the litigation case differs for each type of claim. The justification should state clearly whether the concern is for the penalty claim, the damages claim, or both.

justification:

Step 2: Reduction for Ability to Pay

i. Total Settlement Claim (Penalty, Section I + Damages, Section II) $_____ - Litigation Risk Reduction $_____ = $_____,

i. Total Settlement Claim Adjusted by Litigation Risk - Settlement Respondent Has the Ability to Pay $_____ = Amount Written Off for Ability to Pay $_____.

justification:

IV. Supplemental Environmental Project Offset, if any $_____. The SEP guidance requires separate documentation.